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ROYAL COMMISSION ON MATTERS OF HEALTH AND SAFETY  
ARISING FROM THE USE OF ASBESTOS IN ONTARIO

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Workers

180 Dundas Street  
Toronto, Ontario  
Wednesday,  
July 8, 1981

VOLUME XVII



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ROYAL COMMISSION INTO MATTERS OF HEALTH AND SAFETY

ARISING FROM THE USE OF ASBESTOS IN ONTARIO

VOLUME XVII

INDEX OF WITNESSES:

RICHARD A. LEMEN	Examination-in-chief	Page 4
	Cross-exam (Bazin)	Page 66
	Cross-exam (Jolley)	Page 79
	Cross-exam (McNamee)	Page 94
	Cross-exam (Warren)	Page 111
	Cross-exam (Ublansky)	Page 151

INDEX OF EXHIBITS:

EXHIBIT # 26	Compendium of articles by Mr. Lemen	Page 4
EXHIBIT # 26, TAB 12:	Paper-An Assessment of Epidemiological Literature Related to Worker Exposure to Chrysotile in Mines and Mills	Page 23

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Volume XVIII

THE FURTHER PROCEEDINGS OF THIS INQUIRY  
RESUMED PURSUANT TO ADJOURNMENT

APPEARANCES AS HERETOFORE NOTED

DR. DUPRE: Good morning, ladies and gentlemen.  
Please accept the Commission's apologies for this late start.  
We were unavoidably detained.

It is my great pleasure to greet this morning  
Mr. Richard Lemen, Special Assistant to the Director for Standards  
Development at NIOSH.

Mr. Lemen, I want you to know how grateful we are  
for your kindness in volunteering to come before us here in  
Toronto, to give some sworn expert testimony.

You are most, most welcome indeed, sir.

Counsel, are there any matters before we swear  
in the witness?

MR. LASKIN: I don't believe there are any formal  
matters, Mr. Chairman. We are trying to iron out finally the  
timetable for August, which I think is pretty close to being  
finalized, and I can advise you that shortly.

DR. DUPRE: Thank you.

Miss Kahn, would you swear in the witness,  
please?





RICHARD A. LEMEN, SWORN

EXAMINATION-IN-CHIEF BY MR. LASKIN

5 MR. LASKIN: Dr. Lemen, (sic) you have before you in that red binder a compendium of some of your, but certainly not all of your, publications, but certainly the principal ones relating to asbestos. For the convenience of referring to it, we have given it an exhibit number, and it is exhibit twenty-six.

10 EXHIBIT # 26: The abovementioned document was then produced and marked.

MR. LASKIN: Q. I would like to discuss with you the work of NIOSH, and in particular the two documents which are at tabs two and eleven in exhibit twenty-six.

15 But before I do that, I think it would be certainly helpful to me and helpful to the Commission if you could give us some overview of what the role of NIOSH is, what it's relationship to OSHA is, and what the process of the regulatory function in the United States is at the federal level.

20 THE WITNESS: A. Okay. NIOSH, as well as OSHA, were established in 1970, in the United States, under the Occupational Safety and Health Act. The primary purpose of the National Institute for Occupational Safety and Health, which is located administratively in the Health and Human Services Department and is under the Centers for Disease Control which is located in Atlanta, Georgia, as one of the centers of that Center, is primarily responsible for research directed in the area of  
25 occupational safety and health. As such, the research is then to be translated into recommendations to the Department of Labour for setting standards in the area of occupational safety and health.

30 NIOSH has a joint responsibility in the Department of Labour, with two separate departments of the Department of Labour - the Mine Safety and Health Administration,





5 A. (cont'd.) which is the labour organization that sets standards for miners and for the Occupational Safety and Health Administration, which sets standards for the general workplace.

Our agency makes recommendations to both agencies and setting standards. Again, I would indicate that our agency is not a regulatory agency, nor do we carry any regulatory authority. We are simply a research agency that make recommendations to the two regulatory agencies.

10 Q. Conversely, does OSHA have any research function, or is it simply a regulatory body?

15 A. By law, OSHA is not a research agency. MSHA and OSHA do have individuals with research backgrounds, but they do not perform individual research in either one of the two agencies. NIOSH is assuming that responsibility.

Q. Is there some rationale behind the proposition of dividing off the regulatory function on the one side and the research function to another agency on the other?

20 A. Well, as you may or may not know, in the United States the Environmental Protection Agency has both functions. It has a research and regulatory. We in NIOSH certainly feel happy that we don't have the regulatory function, because we feel that we can then base our recommendations purely upon the health effects data. We do not get into economic considerations. We try and make all the recommendations based upon what we know from the epidemiological and toxicological literature, directing our  
25 comments purely from a health point of view, where OSHA and MSHA have to counter and weigh into the standard the economic analysis.

30 Q. So that when you prepare, when you...when I say you, I mean NIOSH....when it prepares documents such as at tabs two and eleven, I take it then that you are not looking at anything





Q. (cont'd) other than the health effects of the particular substance that you are looking at, that you are inquiring into?

5 A. We are looking at health effects and measurement technique, analytical technique, also.

Q. But you are not looking at, and I take it deliberately so, any type of cost/benefit analysis, any consideration of what uses may be essential with respect to a particular substance, so on and so forth?

10 A. We do look at the different uses of asbestos, and the various substances that we deal with. However, we do not put into it an economic analysis.

Q. Do you have the kind of...what we once called the kind of divided jurisdiction problem that we in some sense have up here? And let me give you an example.

15 If you are talking about a school, does any standard that ultimately comes out of OSHA, is that a standard that would be applicable to the teachers as employees in the school, but would not be, for example, applicable to the students who attend the school?

20 A. That could be a problem. However, under our Act there are some restrictions on government employees and how the Act applies to them. In the case of school teachers, often times they would not be covered under the Occupational Safety and Health Act.

25 But if a standard were promulgated, it could have a difference, it could affect those in the school system. In some of the federal schools where we do have, under the federal executive order, regulation over federal schools, we would possibly set standards for teachers that would not be applicable to students.

30 Q. I take it from what you said earlier that there is a different standard setting body dealing, for example, with



Q. (cont'd.) asbestos, that deals with asbestos in the mines and mills, and a different standard-setting body for asbestos in the general workplace?

A. That is correct.

Q. Can you just again by way of overview help me with how the process of setting a standard gets started, and how it finishes? Is your research, for example, only triggered by a proposal by OSHA as to a particular standard?

A. NIOSH research has been triggered by a variety of different mechanisms. One mechanism is obviously a recommendation from OSHA, or from MSHA, for NIOSH to develop a health effects recommendation for a standard on a particular substance or agent that they have an interest in.

We also receive requests to develop standards, and one example being in the area of vinyl chloride when it was shown to be a cause of angiosarcoma of the liver. The company came to us, asked us to investigate the health effects, which we did do and made a recommendation to the Occupational Safety and Health Administration for a standard. We also get requests to develop standards through various organized labour, through various trade associations, and we also try to develop a priority setting mechanism within our Institute to rank chemicals as to the degree of toxicity, the number of workers exposed, the uses of the chemical or the substance, and through a variety of different mechanisms we come up with what we would term our priority list in making out recommendations.

Q. Do I deduce from the length of time that your proposal or recommendation with respect to asbestos has been on the books that there is no particular time limit within which OSHA must act on any particular recommendation that NIOSH makes?

A. The two laws that govern OSHA and the Mine Safety and Health Administration are somewhat different in that respect. In the Mine Safety and Health Administration, we have





5 A. (cont'd.) once we give them a recommendation, they have sixty days in which to take some form of action on it. They can reject what we have said, send it back for more information. They can promulgate a standard. But they have to make a decision within that sixty day period.

10 With the Occupational Safety and Health Administration, there are no time frames as far as accepting or rejecting the proposals that we make, and I think it's well known to most people that NIOSH has made around...I think the exact number is a hundred and seven standards recommendations, for which less than fourteen, less than a dozen have been developed into standards.

15 So it's a matter that could sit on their books for many, many years, or it's something they could act upon very quickly.

20 Q. You lead me inevitably to ask you, and I'm going to come back to the particular documents you've got, but you are leading me to ask, where is the present recommendation that NIOSH has made with respect to asbestos?

25 A. I think the only people that can legitimately answer that are the current administration at OSHA. The Director of Health Standards at OSHA, Dr. Bailus Walker, in my talks with him has indicated that OSHA is working on a standards recommendation. Beyond that, I can't tell you much more about it. It's my understanding that Dr. Walker has resigned from OSHA, and I don't know what direction that standard will take in the future.

Q. Is there, apart from your recommending function, is there any hearing function that is involved in the setting of the standards, and does labour, does industry, have a chance to have any input...

30 A. Yes. Certainly from the OSHA point of view there is a publication in the Federal Register, and a comment period where any individual or interested party can make comments





A. (cont'd.) back to the Department of Labour.

At NIOSH this is not necessarily true. We try to develop our recommendations by listing in the Federal Register that we are working on them. We then try and get as much representative input from all parties concerned in our recommendation, but we are not under the same type of regulation as OSHA is in getting comments and having a comment period.

Q. Just one more general question. You had indicated to me earlier when we had a chance to discuss things, that NIOSH was to some extent moving away from looking at particular standards for particular individual substances, and as I understood it, and I think it would be helpful to elaborate one it, as I understood it, we are looking more at industrywide approaches to various...whatever substances were in that particular industry.

A. Since I have taken the position that I'm in now, and it's a little bit updated from being Special Assistant. I'm now the Director of the Criteria Documentation and Standards Development Program. In the last year we have tried to look more at, not necessarily just individual substances, but to look at the combination of substances and to look at industries in particular, getting a little bit away from the basic recommendation that we've had in the past of a certain substance at a certain level. We want to look more in depth at control technology, work practices, and the combination of events within a particular industry that lead to adverse health effects that may be occurring within an industry.

So we will still look at individual substances, but we are not limiting our approach...and some of the new documents that we have coming out from our Institute...one in particular on rendering...looks at the total rendering industry from a health and a safety point of view, and makes control technology and work practice recommendations for controlling problems within the industry.



5 A. (cont'd.) This, as far as setting a standard then, is a little bit more difficult than it is when you have just a level and an effect. But we feel as a public health agency that we have a responsibility to make this information knowledgeable to both industry and to the labour movement for their benefit, and working in the workplace. So far, this has been fairly favourable as far as being received by both industry and labour.

10 Q. Have you adopted that kind of approach in any industry where asbestos is a substance that is used?

15 A. We have not formally adopted that. We have, in our health hazard evaluation, certainly made recommendations for control technology and for work practices. In the area of asbestos in particular, what we have proposed have been the recommendations that you have here as tabs, including the one that is not included and which is the early 1972 criteria document.

20 Q. We may get into the particular engineering controls and work practices later in the testimony.

25 Just finally by way of overview, does NIOSH have any role in compensation, whatsoever? I ask that because I noted that your former director gave some testimony before the House of Representatives Committee, looking at compensation.

30 A. I can't answer that completely. I can tell you that it is not our general policy to be involved in worker compensation. We do get asked from time to time to make testimony before a Congressional Committee, but as far as being actively involved in who receives compensation or who does not receive compensation, that's not a part of the role that we play.

35 Q. Do you have any role to play with respect to setting standards in the environment? Do you get consulted by EPA?

40 A. The Environmental Protection Agency, the Consumer Products Safety Administration, all of these agencies tend to come to NIOSH to let us pre-review what they are planning to propose, and ask us to make comment. They have no regulatory...





A. (cont'd.) there is no regulation or legislation indicating that they have to accept our comments. We more or less do it as a courtesy between agencies.

5 We do the same with those agencies on the criteria documents and the current intelligence bulletins and the recommendations that come out of our agency.

10 Q. Can I turn to the two particular documents which are in exhibit twenty-six...that's at tabs two and eleven. I note that both of them contain a very comprehensive review of the literature on the health affects of asbestos and indeed the measurement of asbestos. Can I ask you as a starting question, were there any particular studies, any particular epidemiological studies or measurement studies that you relied on more than others, or that you found more persuasive than others in developing the recommendations that you did?

15 A. I think in looking at the 1972...1976, which is your tab two, and the section which I am not finding right now... the basis for the recommendation of the standard, that you will notice that we listed..

20 Q. Page 88?

A. Page 88. You will notice that we have listed a variety of different reports, and we had relied upon those as being some of the major reports in that recommendation.

25 In the 1980 document, the most recent document, we have outlined...and it's just kind of hard to go into each one separately, I don't think that there is one that I can pull out as being more prevalent...I think it's a combination of these articles that have led us to make the recommendations that we have made.

30 Q. Let me ask you this question: Did NIOSH subject any of the studies to, for example, critical inside evaluation?

A. Every study that we placed in our document we had reviewed by the biostatistical and the epidemiology staff





5 A. (cont'd.) of our Institute. They were not judgements made simply by myself or by other members. They were reviewed by the scientific group within the agency, and in some cases we had persons outside of our Institute look at the studies.

Q. I note that, at least looking at the last two chapters of tab two, that you did appear to place some reliance on animal experimentation with respect to asbestos health affects, and I'm just wondering how significant that evidence was to NIOSH.

10 A. I believe a few comments about our perception of the use of animal studies as compared to human epidemiologic studies may be somewhat in order, and I'll make just a few general comments about that.

15 In the animal studies as compared to the epidemiologic studies, you can certainly control for type of asbestos and for the degree of exposure, for the level of exposure, the extent of exposure, etc. Those types of controls are much more difficult in epidemiologic studies. We are relying on looking at health affects with asbestos that usually take many, many years to manifest themselves. The measurement techniques that were used twenty, thirty years ago differ from  
20 what measurement techniques are today.

25 We did rely very much upon the animal studies in that we could control for the type of fibers that were being used to expose to the animals to. In most of the epidemiologic studies, and I think that Dr. McDonald probably, when he testified before your group, probably gave you a table that broke down the different types of studies. But in the majority of studies that have been done, mixed exposures have occurred and it has been very difficult to feather out those that are related to just chrysotile as compared to amosite, crocidolite, etc.

30 The animal studies provide us an ability to do that, and from that point of view, connecting the animal studies with the human epidemiologic studies, we were able to make some



A. (cont'd.) recommendations that I don't think that we would have necessarily been able to make based upon either alone.

5 Q. That leads me to ask you to ask you about fiber types. As I'm sure you are aware, the British, by way of example, have taken quite a different approach with respect to standards in the workplace, by differentiating as amongst fiber, and indeed this jurisdiction has proposed a similar differentiation as amongst fiber types.

10 Can you help us a little more on what the thinking was of your group, as to why you didn't make the differentiation?

A. I think that several factors came into play here. We reviewed most of the literature. We relied fairly heavily on information from the expert committee set up by the IARC volume, looking at the animal studies as well as the human studies.

15 Q. That's your tab five?

A. I don't remember which tab it is. Yes, tab five. Which was a fairly comprehensive review put together by a group of experts which are listed in the beginning of that document, indicating that both in the animal studies and the human studies that we were seeing effects from all the commercial forms of asbestos.

20 As a matter of fact, we had found in animal studies that the effects of chrysotile were somewhat worse than the effects of some of the other fiber types, and we felt that even though the human epidemiologic literature tend to be used to say that crocidolite and other fiber types are more dangerous, we do not necessarily feel that that is supportable because most of those studies were done on populations with mixed exposures and very few were dealing with just chrysotile alone.

25 There are some new studies out...the Dement study is an example...I think that that is an epidemiologic study that will indicate that at least in the textile industry there should





A. (cont'd.) be concern for health effects associated with chrysotile.

5 We felt that those studies, as outlined in our document, justified the need to have an overall standard for one fiber type and not limited to single fiber types. Our personal feeling was that the British were making a decision without all the evidence brought into play yet.

10 Q. Can you just expand on that a bit by helping us as to what evidence you believe the British overlooked in their deliberations?

15 A. I think they misunderstood the epidemiologic studies on chrysotile as compared to crocidolite. I think that, as I said earlier, that the combination, the mixed fiber types that were in the studies, overwhelmingly led them to believe that the chrysotile is more dangerous. However, the Medical Research Council in Great Britain has done animal studies which indicate just the opposite for chrysotile, that chrysotile is a hazard particularly in the situation where you have brought the material into the textile plant or in those areas.

20 I, again, would say that the McDonald studies which are looking at miners, there may be some alteration of the fiber once it has come from the mine, gone through the mill into the textile plant or into the insulation plant, or wherever it may be used, and I think these factors were not necessarily clearly considered. I can certainly see that there may be some differentiation between mining situations as compared to situations in general industry.

25 Q. I want to come to that in a moment, but you having mentioned Dr. McDonald, in his testimony before us a couple of weeks ago his proposition was, indeed, that we should consider banning the amphiboles and then look at setting some appropriate standard for chrysotile, and I don't think I'm misquoting him.

30 One of the things that he pointed to was the apparently low



5 Q. (cont'd.) incidence of mesothelioma with the use of chrysotile, and indeed supported that by looking at Dr. Dement's recent study where I gather there was only one mesothelioma found amongst, I think it was, if my memory serves me correctly, about a hundred and ninety-nine or two hundred deaths. Do you have any comment on that?

10 A. Not a lot of comment. I think in the area of mesothelioma that there may be some differentiation. Again, I don't think all the data is in.

15 In a study that we had done in a predominantly chrysotile...and I'll make no suggestion that it was purely chrysotile...but we do know those workers that had chrysotile almost exclusively as compared to those that had exposure to the amphiboles, that in our initial study which we had completed in 1971, we had very few mesothelioma. In an update of that study some eight years later, eight more years of followup when the latency period expanded, we had seventeen mesotheliomas.

20 It may well be that in the area of chrysotile that there are competing factors, one being that the latency period may be much longer. It may be that there may be other causes of death that are not allowing that to occur, because in the heavily-exposed textile areas, we see a lot of asbestosis, we see quite a bit of lung cancer.

25 I don't necessarily think you can base a recommendation just upon the fact that you have a low instance in mesothelioma. Certainly lung cancer is still a hazard, and I think just as important a hazard, as the mesothelioma.

Q. The study that you just referred to, is that your own study out of Lancaster, Pennsylvania?

30 A. Right. There are two papers that you have, one that was prepared for the Congressional record and submitted by Senator Taft in 1971, in the Respiratory Disease Benefit Act, and was never published other than at that location. The second





A. (cont'd.) was a study that was done in 1976, Robinson was the senior author on that.

Q. You say it has now been updated to...

A. No, those are the two studies.

Q. Those are the two studies?

A. That's correct. 1979, I'm sorry.

MR. WARREN: What's the tab number on that?

MR. LASKIN: I think the first one is at tab one...

THE WITNESS: And tab six.

MR. LASKIN: And tab six.

THE WITNESS: One and six.

That was updated through 1976, I'm sorry.

MR. LASKIN: Q. Through 1976.

You say it was predominantly chrysotile, but there may have been...

THE WITNESS: A. There was a short period of time in that population during the war years where amphiboles were used because of the inability to get enough chrysotile in certain areas. Other than that, and we've been able to pretty much isolate the areas in the plant where those were used, it was primarily chrysotile.

It was a sister plant to the plant that John Dement studied in South Carolina and Charleston.

Q. The same company?

A. The same company, and essentially the same type of process, with some alterations.

Q. Just as a matter of curiosity, with respect to the seventeen mesotheliomas, were you able to isolate an exposure to chrysotile in any one or more of them?

A. Again, that's one of the difficulties, and we are in the process of trying to look at some of the tissue to see what type of fiber is in the tissue. But we don't have all the answers in on that at the present time.



5 Q. I take it as a practical matter, from looking at your IARC document, that the amount of amphiboles actually used in the United States at the present time is very small, relatively speaking?

10 A. It's our understanding, and I think the Department of Interior, Bureau of Mines, is probably the place to get the correct answer, but I think that chrysotile, and maybe some of the people in the audience have better knowledge than I, is the predominantly used fiber in manufacturing situations.

15 Q. Perhaps I can just take you for a brief moment to tab five, and there is a table...I take it you prepared an original draft, that you were the person who originally drafted the paper which is at tab five?

20 A. I wrote the original draft of the...yes, monograph.

25 Q. There is a table at page thirty-one which appears to set out the uses of asbestos by fiber type, in the United States in 1974. Do you...I appreciate, Dr. Lemen, you may be a little divorced from the particular matters you look at... but do you have any idea as to whether this kind of distribution would have changed to any significant extent in the last seven years?

30 A. I can only make presumptions. I don't have the data in front of me to back it up, and I would refer to Dr. Chase or other members of the industry that are here today, but I would think that probably the use of crocidolite in the United States has probably gone down somewhat.

I would expect that anthophyllite and amosite probably remain somewhat the same, and I would expect that chrysotile is probably remaining somewhat the same, or increasing proportionately to the demand. But I, again, would refer you to refer that question to some of the industry people that are using the material.





5 Q. Has NIOSH...I'll ask you this question...has NIOSH looked at the question as to whether crocidolite is necessary in the manufacture of asbestos cement pipe? Is that a kind of issue that NIOSH would get into, looking at that sort of question?

A. Not necessarily. We would tend to stay away from that. We have looked at substitute materials, but not necessarily looking at their application. That's more in the area of the industrial engineer, and NIOSH traditionally has not been in the field.

10 Q. Fair enough.

15 There is a statement in tab two that when you came to the recommendation of point one fiber per cubic centimeter that it was your view that it would protect against asbestosis, or prevent asbestosis. May I ask you whether in making that statement you were intending to suggest that at least for asbestosis there was some threshold below which it would not occur?

20 A. Certainly we feel that the lower the exposure, the less disease that's going to occur. That's true for nonmalignant as well as malignant disease. We do think that there is probably a level that, below which you will probably not get adverse affects such as asbestosis.

25 The epidemiologic literature, if you look at it, and the toxicological literature, have shown that basically at all levels of asbestos exposure studied, health effects such as malignant disease have occurred. We do feel that the low level of the point one recommendation we have made will protect for asbestosis, but not for cancer. Those are based on both toxicology and epidemiology.

30 Q. Were you of the view that there was any less stringent standard that would have protected against asbestosis, and I'll leave aside lung cancer for the moment?

A. Obviously we felt in 1976, in our original one, criteria document, that the two fiber level would, but the



5 A. (cont'd.) British information and some of the newer information on pulmonary function and x-ray examination of family members would indicate that that is probably not adequate for protection against asbestosis.

Q. I take it that at least in respect of lung cancer that you assumed a dose-response relationship that ultimately went through the zero intercept on the Y axis?

10 A. I think that we stated that the linear relationship appeared to be the best, and that did go to that level.

Q. Did you attempt to make any quantitative assessment of what kind of excess risk there would be at the point one fiber standard?

15 A. We did not. We are in the process of now doing that.

Q. Of doing a quantitative risk assessment?

A. Yes.

Q. Can you help us as to how you are going about that?

20 A. Well, we are looking at the various studies that have been done, and looking at our modelling to make predictions, going through the linear relationship as well as other types of dose-response curves. I think very honestly, it's too soon to indicate what the results of that would be.

25 We have some preliminary information which we have developed for the Mine Safety and Health Administration, which would indicate that we would expect at least a one-to-seven percent excess lifetime lung cancer mortality risk among workers of mixed smoking status who have been exposed to chrysotile at the current U.S. federal standard of two fibers per c.c. for twenty-five years by the age of forty-five.

30 I can make this report available to your committee, and we are in the process of finalizing this report. But I would indicate it is preliminary at this point.





Q. I think that would be helpful.

Can you help us as to what the model was that you relied upon to come up with that estimate?

5 A. I don't know how much you want to go into models. That's kind of a broad question, as any person in statistics would know.

Q. It's my naive way of asking it, Dr. Lemen. I don't know what I'm getting myself into by asking it.

10 A. We were using basically a linear model, and we were using some...with that type of analysis. I don't know how much more detail you want to go into on that.

Q. All right. Were you looking...I take it that it has to be an extrapolation? Is that accurate?

A. That's true. That's true.

15 Q. All right. Was it an extrapolation from the particular statistics or the particular study of any cohort?

A. This analysis was based upon four different studies. One is the McDonald study, which I can give you the exact references, if you would like...the McDonald study in 1980, titled Dust-Exposure Mortality in Chrysotile Mining.

20 Q. That's the British Journal of Industrial Medicine...

A. Right, the British Journal of Industrial Medicine.

25 The second study, and it was the Rubino et al study in the British Journal of Industrial Medicine, 1979, A Mortality of Chrysotile Asbestos Workers in Northern Italy.

The third study was one by Nicholson, etc., titled Long-Term Mortality Experience of Chrysotile Miners and Millers in the Thetford Mines in Quebec. That appeared in the Annals of the New York Academy of Sciences, 1976.

30 The fourth study was the unpublished, at that time, doctoral dissertation of John Dement.



Q. That, I take it, was not a mining study, but that's his textile plant study?

A. That's correct. This analysis for our Institute was done by Dr. Michael Allalonya, Chris New and Judy Parsells, all three epidemiologists in our Institute.

I personally did not have anything to do with this analysis. I asked that it be done independent.

Q. Can you just run by me again the figure, the excess risk estimate that you came up with?

A. I can read you the conclusion of the entire report. There are basically four conclusions, and I would be happy...and this was prepared for the Mine Safety and Health Administration and it will be a part of our standards package that will go to them.

The first conclusion was: "That an assessment of mortality risk due to occupational exposure to chrysotile in mines alone could not be made."  
In other words, we are talking about mixed fiber types.

"Two, that the study by McDonald, et al, entitled Dust Exposure and Mortality in Chrysotile Mining, is the most comprehensive and reliable study available to assess the mortality experience of workers in chrysotile mines and mills. Design characteristics of this study produce an underestimation of the excess mortality due to occupational exposure.

Three, lung cancer mortality is the most useful outcome variable upon which we can base a mortality risk assessment for chrysotile miners and millers. Fourth,...is the one that I read to you..."That assuming dust-to-fiber conversion factors utilized in this report are valid, we would expect





5 A. (contd.) "at least a one to seven percent excess lifetime lung cancer mortality risk among workers of mixed smoking status, who have been exposed to chrysotile at the current U.S. federal standard of two fibers per c.c. for twenty-five years by age forty-five.

Additionally, occupationally-related deaths would be expected from asbestosis and mesotheliomas."

10 Again, this report I will give to you. We have it in the process of getting some peer review at the present time and it is still a preliminary report.

Q. When you say you will give it to us, can that... is it available to us for the purpose of our public record today?

15 A. Anything done within our Institute is available under our Freedom of Information Act.

DR. UFFEN: Just for clarification, that last one is quite a mouthful to digest. But you said that assuming the conversion factor, is it...what was...was there a single conversion factor and do you remember what it was?

20 THE WITNESS: Well, I think that when you have Dr. Dement here, he can go into that in much more detail. He used a variety of conversion factors based upon information that NIOSH had collected in a variety of studies, in putting impinger samples next to the personal samples measured on membrane filter, and for different operations, different conversion factors were used.

25 MR. LASKIN: Q. Can I come back, just before I forget it, to the second conclusion, which intrigues us a great deal?

30 DR. MUSTARD: Counsel, can I interject for a moment? It would help, I think, some of us if we had a copy of that abstract that he is reading from...if that's not too difficult to do.



MR. LASKIN: Would the Commission like to take about five minutes, and I could xerox the last four...well we'll get the whole thing, but certainly the last four conclusions. I think that would help everybody.

DR. DUPRE: It would be helpful.

THE INQUIRY RECESSED

THE INQUIRY RESUMED

MR. LASKIN: Are we ready?

DR. DUPRE: I think the Commission is just waiting for its own copies.

MR. LASKIN: Oh.

DR. DUPRE: Are you going to wish to assign that...

MR. LASKIN: Yes. While Linda is handing them out, let's identify this document.

First of all Dr. Lemen, can you identify what the document is and what its purpose is, and then we'll give it an exhibit number.

THE WITNESS: What I would like to say, and I should have said earlier about this document, that it is an internal document within NIOSH, that I requested be done by a group of our epidemiologists. It does not in any way, respect, represent any official opinion of our Institute. It's in the process of peer review at the present time, and we have sent it to persons outside the Institute, as well as inside the Institute, for that peer review, and it remains to be seen what the distribution will be after that peer review comes in. That there will be possibly modifications, and I request any of you that have received copies of this to feel free to contact us about this document.

But the intent is to make available to you as much information as our Institute has in the area of asbestos,





THE WITNESS: (cont'd.) any new information that you can look at, and you can make your own determinations...and we are, again, very receptive to your opinions on this.

5 MR. LASKIN: Thank you very much. That's very kind of you.

Well, the document is entitled An Assessment of the Epidemiological Literature Related to Worker Exposure to Chrysotile in Mines and Mills, and bearing in mind Mr. Warren, perhaps we should give it a number as tab twelve in exhibit  
10 twenty-six.

MR. WARREN: John, this will be for the entire document, that tab number? Not for simply...

MR. LASKIN: Yes, it will, Ed, and that entire document, as I understand it, will be available by lunchtime so  
15 that we will have it for the purposes of this afternoon.

MR. WARREN: Good.

EXHIBIT # 26, TAB 12: The abovementioned document was then produced and marked.

MR. LASKIN: Q. Dr. Lemen, I appreciate that  
20 you didn't actually write this document, and I take it were not personally involved in preparing it. May I ask you a few questions about the conclusions, if you are able to help us on some of them?

Can I ask you, with respect to the first one, I'm not entirely clear as to what is intended by the first conclusion.

25 THE WITNESS: A. I think that you have to understand that the information and the reports used deals more than just in mines. It deals with mills, millers and, with the case of the Dement study, certainly deals with the textile facility that in no way should be represented as being representative of what  
30 a situation in a mine would be.

Q. I see.



A. We are dealing with chrysotile as a general substance.

Q. I see. Do I...

A. The point we are making is that we don't feel the data is available to make an analysis just in the mining area.

Q. All right. Do I take it that one of the conclusions that flows from that is that your group, or the people that put this paper together, were not satisfied that McDonald's study alone was sufficient to make that kind of estimate?

A. I think point number two states that, saying they felt that McDonald was the most comprehensive and reliable, but it did have some problems that they felt made it not reliable enough to make an estimation purely based upon that one study.

Q. Can you help us as to what considerations, what factors they felt produced the underestimation and made it not sufficiently reliable?

A. I think that the details of that can be found in the report that, just to summarize very briefly, I believe that they felt that there were some dilution characteristics by including persons with shorter latency periods, etc., and in some of the measurement techniques that had been utilized. I think it was primarily based upon the makeup of the cohort that was used in the study.

Q. You have indicated that Dr. Dement, assuming hopefully that he comes and testifies before us, would be able to help us with the question of fiber conversions?

A. I think that in our Institute he is the most appropriate. I can certainly tell you a few things about fiber conversion if you would like some general comments from my experience.

Q. Yes. Very much so.

A. John Dement and I, in 1972, looked at the paper





5 A. (cont'd.) that was presented by Howard Eyre, I think, in the American Industrial Hygiene Association Journal... I may be incorrect on that, and I'll get you the correct reference... where he had looked at conversion factors and had come up, I believe, with the conversion factor of six, comparing MPPCF to fibers per c.c.

10 We started doing, in our Institute...primarily John Dement did this...some comparison sampling, and found that across the board if you looked at all operations you could be off by a factor of fifty percent or higher in either direction, utilizing this number.

15 We concluded at that point in time that there was really not a reliable single conversion factor to use, and in the paper that John Dement has done this last year, he did some more of the side-by-side sampling and was able to look at area by area, and making separate conversion factors from one area to another area.

I was going to...

Q. You mean area by area within a single plant?

20 A. Right. Let me read to you just one point that he made which may clarify this to a certain extent.

25 He said that there were two relatively good sources of data for making this kind of estimate. One was a hundred and twenty paired impinger memberane filter samples collected in the plant that he studied, by the United States Public Health Service, between the years 1965, and this included... it wasn't between years, it was in 1965...and included nine hundred and eighty-six concurrent samples by the two methods, in plant operations, collected during 1968 to 1971.

30 "Relationships between the two methods were investigated using the multiple linear regression results of these conversion estimates, and approximately ninety-five percent confidence intervals



A. (cont'd.) "are given in figure one."

Do you have this report?

Q. It is exhibit four, already in our proceedings.

A. ... "are given in figure one. For all textile operations except preparation, a conversion of three fibers per c.c. for one million particle per cubic foot was used,

For preparation, a conversion of eight was used.

Using these conversion values, all sample data were expressed in fibers per c.c."

I think that this indicates a little bit of what we know about the textile industry. In the fiber preparation area, it is certainly the more dusty area and you get a different variety of fiber sizes in that area as compared to when you get further down the process line when you are dealing with fibers that are more in a general fiber range than what you get when you are pouring just everything from the burlap bag, or whichever type of bag you have, into the hopper in the fiber preparation area.

So he made a fairly good estimate, but my general impression is that there is not any way that you can come up with a single number for that conversion value. You've got to look at what the methods are. The impinger method measures total dust. The membrane filter measures fibers...not necessarily only asbestos fibers, but it measures fibers.

The difference between total dust and a fiber can vary from a magnitude of fifty percent or more, and I think that just the basic principles of the two analytical techniques should tell most that it would be improbable that you would come up with one fixed number for that conversion.

And that's what makes it extremely difficult in our epidemiologic studies to relate health effects to exposure levels thirty years ago.





Q. When you prepared the criteria documents for OSHA, did NIOSH attempt to apply conversion factors to any of the studies that were based on particle count?

5 A. Not to the extent that Dr. Dement did in his study. We based ours on the information that we could obtain through the fiber counting method and through just general dust and trying to recreate historically, as best we could, what the measurements would have been.

10 Q. Coming back to tab twelve of exhibit twenty-six for a moment, do the authors come up with a conclusion or recommendation as to what the appropriate standards should be in the mines and mills, or is that something...

15 A. This document was not intended to do that. This document was intended purely to take the four reports and to look at them and come up with some type of a risk estimate based upon those reports, and had no intent of being a recommendation for a standard.

20 Q. Are there risk estimates that...I haven't got the report in front of me...are there risk estimates at other hypothetical levels, other fiber levels?

A. We, at our Institute, have not developed that at this time.

Q. That is ongoing?

A. That is ongoing.

Q. That is ongoing.

25 Can I ask you, is there a standard in place in the United States in the mines and mills?

A. That's a good question. I can't really honestly answer that to tell you what the level is.

I'm sorry. Maybe...is it two?

Q. Ed seems to be nodding.

30 Has NIOSH, for example, prepared any separate criteria documents for the mines and mills?



A. NIOSH is in the process of preparing a criteria document on mines right now.

Q. Asbestos mines?

A. Yes.

Q. Any idea of when...

A. The timetable is sometime in the next year.

We hope to have it out in 1982. We have a variety of people within our Institute working on a document, from different divisions, and I would be happy to give to you the work plan for that document. I don't have it with me today, and again that's a matter of public record and I would be happy to give that to anyone who would like to see it.

Q. I think that might be very helpful.

DR. DUPRE: Counsel, could I just ask one question about this?

MR. LASKIN: Certainly, Mr. Chairman.

DR. DUPRE: Mr. Lemen, when you get to the summary point number four, I just note the way it's written on the bottom line, the bottom line on the first page.

"Excess lifetime lung cancer mortality risk among workers of mixed smoking status"...etc.

Is this meant to convey among workers at any step in the asbestos industry? In any segment of it? Or among workers in mining and milling of mixed smoking status, etc.?

THE WITNESS: We are talking about across the board from these four studies.

DR. DUPRE: There you are talking on that, number four, you are talking...

Thank you, counsel.

MR. LASKIN: Q. Just so that I am clear, now that the chairman has raised that last point, the estimate that you have made here is an estimate that may apply to...that the authors intended to apply to textile plants in the same manner as mines and mills?





THE WITNESS: A. Based on four studies that are surveyed, it has no intent to go beyond the four studies that are in the document. This is the risk that these four studies would indicate could be the lifetime risk of developing lung cancer.

And I think that you have to keep in mind that if you try and take this beyond the four studies you are going to be in a great deal of difficulty, because it is not intended to do that. This is an analysis of those studies.

Q. But in coming to the figure of one to seven percent, did you, for the purpose of calculating that figure, accept the risk estimates that were produced in each of the four studies, and I ask that because of the second conclusion which is that McDonald is an underestimate..but for the purpose of preparing that figure or coming to that estimate, did you accept his...

A. To the best of my knowledge, that's true.

Q. Equally, you accepted whatever risk assessments were made in the other three studies?

A. Yes.

Q. Can you just finally, can you tell me was there any premeditation in selecting the four studies that you selected? As opposed to any other studies?

A. Well, the first three studies were obviously selected dealing with mines, and the studies were based upon studies that had available information that could be used for risk assessment in the area of chrysotile exposure. From that point of view you could say there was premeditation in the selection of the studies.

Q. The Dement study was selected for what reason?

A. The Dement study was selected because it had built into it a good risk assessment, and it dealt with the pure chrysotile exposure. If you read the document, you will find



A. (cont'd.) that those are treated separately, the mining studies from the Dement study, and that is very clear. They are differentiated in the document.

5 Q. Was any consideration given by way of comparison to looking at the Rochdale textile plant in England, and those studies that have looked at that plant?

A. In this particular document, it was not a matter that was...we did not use the data from that plant.

10 Q. Was there any particular reason why not?

A. I can't really give you a good answer on that. I'm sorry.

15 Q. Can we turn to...perhaps it's a subject that flows out of some of these studies...and this is the fact that you do see different results in different studies, and one of the things that has been put to us by other expert witnesses who have come here before us is, the farther you get away from the mine, downstream, through manufacturing into ultimate user applications of asbestos, generally speaking the higher the excess risk, or the relative risk seems to be greater to asbestos-related diseases, and can I ask you first of all is that a fair  
20 general statement, from your own knowledge of the various studies?

A. I think we...I need to keep it in one context, the studies that we have evaluated and the studies that we have looked at have generally dealt with occupational setting and not consumer use of asbestos-containing products. So that any  
25 statements I make would be based upon what we have seen in the occupational setting.

Q. When I said user, and I perhaps used an inappropriate word myself, I meant insulation work, the application of asbestos rather than a manufacturing situation.

30 A. I certainly think that the type of fiber that you find in a mining situation is different than the type of fiber you find in the general industry situation, and I've said





5 A. (cont'd.) this before. Not all people would agree with that, but I think that once the fiber has been milled and further processed, it takes a different characteristic. It separates fibers into the smaller fibers, breaks them, etc., and that the more exposure that occurs to fibers that are in a respirable range, that people can breathe or can ingest, I think that you see that the health effects get a little bit greater than what you see in areas where you have a chunk of fiber that is very difficult to get into the nose, etc.

10 So I think that certainly different manufacturing processes alter the fiber, and I think that the people at Johns-Manville have certainly said that in many of their reports.

Q. Alter it both in terms of its diameter and in terms of its length?

15 A. And length, that's correct.

Q. I understand that the...

A. Well, as far as diameter, that's a little bit hard to alter. But as far as length, certainly.

20 But fiber diameter could...you know, it can break into fibrils and then can take on a different characteristic.

Q. That's one of the propositions that has been put to us, and that as you go through the process that the fiber will break off into fibrils which are of finer diameter and therefore more easily respirable.

A. That's correct.

25 Q. Is that one of the things that you have been intending to suggest?

A. That's what I am saying, yes.

Q. What about on the question of fiber length? Is it the short fibers or the longer fibers that are, in your judgement, more hazardous?

30 A. I think that the opinion that most of the scientists in our group would have would be that up to a hundred



5 A. (cont'd.) microns in length you can get into the respiratory tract. But the longer the fiber, the less the chances are, so that the shorter fiber obviously, from our point of view, is one that we would be more concerned with.

10 Q. Can I ask you one other measurement question, and I take it that, and we have been told, that the standard index measurement on the optical microscope of fibers greater than five microns in length, with a three-to-one or greater aspect ratio is but a small proportion of the number of fibers or fibrils that you may actually have.

15 Can I ask you whether, in any given sample that you might measure, whether the proportion of fibers that you are not measuring, or fibrils that you are not measuring, relative to the ones that you are actually measuring, changes, for example, in the mining situation as opposed to the manufacturing situation?

20 A. Well, let me take the answer a little bit indirectly. Looking at manufacturing plants, we have done the traditional phase contrast greater-than-five-micron-in-length analysis, and we have come up with a fiber count.

25 We have also taken those same samples and characterized them by length, and in many cases we have found up to ninety percent are less than five micron in length.

So one would...

Q. Under an electron microscope?

30 A. Yes. And when we are counting fibers at the five micron in length, we may well be getting a misleading...we may have a much higher concentration of respirable fibers than what we are saying, but we have continued to stay with the five micron length because of the feasibility of that analytical technique, and we have stated that very clearly in both the 1976 document and in our new document, the OSHA/NIOSH working group.

As far as sampling differences between the mining situation and the general industry situation, I would refer that



A. (cont'd.) question to some of our people that have been doing that analytical analysis. I don't feel that I am appropriate to make that judgement.

5 Q. As to whether in any given sample there may be a larger, for example, proportion of smaller fibers relative to the ones that are actually being measured. Is there any difference in that kind of distribution as between fiber types, to your knowledge? I mean, for example, if you are dealing with the amphiboles are you likely to see more smaller fibers  
10 relative to the ones that you are actually measuring?

A. Again, I had indicated to you earlier, I don't have...this isn't an area that I have a lot of expertise in and I refer that to our experts in analysis. I can give you some of the names of people in our Institute, but...that can address that question more adequately.

15 Q. Fair enough.

You also indicated that NIOSH's recommendation, as I take it, is to continue with the use of the optical microscope and the measurement of fibers greater than five microns in length, in the workplace?

20 A. We indicate in our latest document that we recommend the use of the phase contrast microscope. We also recommend, because it counts fibers and sometimes you cannot rest assured that it's asbestos fibers compared to some other type of fiber, that an electron microscope analysis or other type of analytical technique be used to identify in the  
25 particular plant you are in what type of fibers you are talking about.

But as far as a compliance recommendation, we recommend to OSHA that they continue to use the phase contrast microscope.

30 DR. UFFEN: Could I determine, is it my misunderstanding or it seemed to me a slight inconsistency here.





5 DR. UFFEN: (cont'd.) A few minutes ago you were telling us about the importance of the very small fibers, but you are sticking to the recommendation of the greater than five microns because of the availability of the phase contrast microscope technique?

10 THE WITNESS: It's based primarily on the availability of the phase contrast microscope technique, and the easy access and utilization of that microscope as compared to the electron microscope.

DR. UFFEN: Even though it leaves out these potentially...

THE WITNESS: That's true.

DR. UFFEN: ...important small...

15 THE WITNESS: We point that out very clearly, that it does leave that out, and we still recommend the use of that technique, supplementing with the electron microscope, but on a routine monitoring basis we recommend the use of the phase contrast.

20 DR. UFFEN: The thing that I have difficulty with is, you use as your general principal that standards should be set at the lowest detectable level. Then we go to a measurement technique that doesn't give us the lowest detectable level.

25 What this seems to suggest to me is that any regulation based that way is going to have to be changed as soon as we have a better method of detection.

THE WITNESS: We are recommending the lowest detectable level with the phase contrast microscope, not the lowest detectable level period - lowest detectable level with the phase contrast microscope.

30 MR. LASKIN: Q. If the phase contrast microscope, hypothetically, were able to detect a level at say point zero zero zero one fiber per c.c., as I read your document, and I may



Q. (contd.) have read it incorrectly, you would propose that standard from a health risk point of view?

THE WITNESS: A. Yes.

5 I might add a little bit about the policy of our Institute in dealing with carcinogens, and that policy is from a health risk and based upon many reports, plus our own internal analysis. Not mine, but the Institute's position, is that we feel that anything that is shown to be carcinogenic, that we determine is carcinogenic, should be controlled to the lowest  
10 feasible level based upon the analytical technique that is available for that particular substance, and we are not taking, again, economics into account. We are talking about from a purely health risk, we have accepted that there is no risk below which you will not see some carcinogenic potential in some  
15 individuals, and we based that on reports from the Public Health Service and from reports from other independent research agencies, plus our own, and at the current time that is the policy of our Institute. That may change at some future point, but that is our current philosophy.

20 Q. If there are issues with respect to any particular substance, as for example whether any particular standard that you recommend is achievable in the workplace in a practical sense, or whether there are economic considerations that ought to be taken into account, as for example the cost of meeting a particular standard, who in the process of setting the  
25 standard takes those considerations into account?

A. You mean the economic considerations?

Q. Yes, or the technological or practical considerations?

A. That is purely in the Department of Labour's hands. That is not in our hands.

30 Q. That would be then OSHA?

A. OSHA or MSHA.





Q. Can you give us any sense as to whether that is the kind of division in trying to set a standard...

5 A. I think that back to...and there are people here that are much more knowledgeable than I...but the benzene decision. But going back to that, that certainly forced us to do...

Q. We have someone who, I gather, is very knowledgeable about that decision.

10 A. That certainly forced us to make a new determination, and in every package that we put out a criteria document to the Department of Labour, we will have included in that package from now on a quantitative risk assessment. There are a lot of controversies in the United States, as well as other countries, about how you do quantitative risk assessment. I don't think any one person has an individual answer on that.

15 You are going to see a multitude of different techniques used for quantitative risk assessment. You are going to see linear models, you are going to see other types of models that are used. We have a team within our Institute trying to develop some assessment of how we would do quantitative risk assessment, and it's a very difficult thing to do.

20 But in any future document you see us come out with, from a health point of view we will say at the current standard, if it's dealing with a substance, this is what the information we have available to us indicates the health risk is. If you reduce the standard by a magnitude of five, this is what we see the health risk to be...the magnitude by another factor, this is what we see it.

25 We will give many different levels of risk that we will come out then...based upon whether it's a carcinogen or a noncarcinogen, with what we feel is a public health policy as to what level the standard should be set at. But we will give a range of risk associated with different levels.



Q. Is that analysis an outcome of Mr. Warren's success in the United States Supreme Court?

5 A. Quite inevitably, yes. Our Institute has not done that in the past, and to my knowledge none of the other institutes.

I might say from my point of view that I don't think that's bad. I think it's a good decision and I support it.

10 Q. I take it you are now in the process of doing precisely that with respect to asbestos?

15 A. We are doing that with asbestos, and we will be sending our recommendations to OSHA with a quantitative risk assessment. We are also doing quantitative risk assessment on several others, and I don't hesitate to say that anything we put out when we are dealing with numbers are going to arouse a great deal of controversy, and the statisticians are going to be playing with it for years to come. But we will make those determinations.

MR. LASKIN: Did you have a question, Mr. Chairman? You were looking...

20 DR. DUPRE: No, counsel.

MR. LASKIN: Q. Can I come back again to a discussion of some of the differences amongst these various studies...not in any general detail, but can I put to you some other propositions that have been suggested to us by previous witnesses, for your comments?

25 There has been, apparently, in some of the literature, a theory that there may be a cocarcinogen involved, interacting with asbestos as you move away from the mine and get into manufacturing processes, or into uses or applications of asbestos.

30 Has NIOSH looked at that question, and if so, what is its judgement?

THE WITNESS: A. When I first came to the Institute



5 A. (cont'd.) in 1970, and the predecessor organization, which was the Bureau of Occupational Safety and Health, had been doing a great deal of research in the area of trace metals attached to the fiber, looking at nickel and magnesium, other types of metals...and looking at the carcinogenic potential of these.

10 That information is available in the scientific literature and it comes to various conclusions. Obviously, that some of the metals attached are carcinogenic, and feel that it could play some role.

15 We have continued to look in this area, at our Institute, at trace metals and other interactions with asbestos, and we have looked very closely at the work at NCI and the Stanton work where Stanton looked at different types of fibers and found that it was more on the characteristics of the fiber than on what was necessarily attached to the fiber.

20 We feel from a physiological point of view that certainly the scarring that occurs in the lung from the fibers is due more to the physiological characteristic than the type of metal that it may carry on it. I don't think that anyone would argue that smoking has an interaction with asbestos, and I'm not here to say that attaching some other chemical or substance onto the fiber doesn't increase the risk, but I think that we feel that the fiber alone is sufficient to cause pulmonary fibrosis and malignant disease.

25 But certainly there are those schools of thought that feel that those disease are increased with certain combinations of materials attached to the fiber, or certain personal habits associated with people that are exposed to those fibers.

30 I think that's as general as you can sum it up and as precise as you can really get.

Q. Can I ask you just one other question, leaving





Q. (cont'd.) aside tobacco or smoking, on which we have had a considerable amount of evidence.

5 In the literature, from your knowledge are there any other particular substances that you can identify as being put forward as interacting synergistically with asbestos?

10 A. As you have seen, the earlier literature, benzopyrene and other compounds used do increase the incidence of tumor, some of them. Metals, again, that are attached to the fiber are known by themselves to cause cancer. I think that certainly you can find examples in the scientific literature of cases where the potential for tumor induction or fibrosis have been increased by different types of materials that have been used in conjunction with a fiber. It's not, by any means, that clear cut in the epidemiologic literature, but in the animal studies I think you could find representative samples to show what you are saying.

15 Q. Do you have any judgement as to whether the fiber itself goes through any change in its physical state or any change in its integrity, in various applications that may affect its toxicity? Is that a consideration?

20 A. Well, as I indicated earlier, I do feel that there is a difference between the fiber that you find in the mining situation and the fiber that you find during the milling and in the general industry situation. As far as fiber taking on different characteristics, what you do to the fiber in the milling really determines the kind of characteristic that it takes on and the type of application that you put the fiber into determines the type of characteristic it takes on. So

25 certainly I think it's very clear to say that fiber takes on different characteristics in different occupational situations.

30 Q. When you say different characteristics, is it something more than a different size or shape?

A. I'm talking about primarily size and shape. I'm sure that there are applications where you can add certain



5 A. (cont'd.) trace metals will be on the fiber as compared to certain trace metals that would not be on a fiber, or certain other things would be attached. But I'm restricting my comments primarily to the physical characteristics of the fiber.

10 Q. Can I ask you another question about various aspects of the asbestos industry? Another proposition that has been put to us is that certain classes of workers, in particular insulation workers and maintenance workers, because apparently they get or may be subject to very intense doses of exposure for very short periods of time, may be at higher risk than the worker who would get the same exposure but spread out over a longer period. Do you have a professional opinion on that question?

15 A. I think general industrial hygiene observations can answer that question, and one observation is that maintenance personnel tend to get involved in all forms of the operation. They are not restricted to preparation, if you are talking about textile as compared to weaving or finishing, but they come into the situation to either clean up or to repair equipment that has broken down and they have a multitude of exposures across the plant, and traditionally we have seen that maintenance  
20 personnel tend to have, in some occupations, higher disease rates than do people that are located in other parts of the plant.

25 I think that's just a general statement that could apply to the asbestos industry as well as to the chemical industry or any industry, and I have not seen anything in the asbestos literature to indicate to me that that doesn't accrue there also.

Q. From what you've said, is it a function of the intensity of dose, or is it a function of something else, or can you say?

30 A. We stated very clearly in this document that obviously the higher the dose, the greater the chance of disease. So I think that the intensity, as well as the duration of exposure, have a great deal to do with the development of disease.





5 A. (cont'd.) And I think it has to do with the type of disease that may develop. I think that those who have very intense exposures tend to get more of the fibrotic disease and may die from that before they have had an adequate latency period to develop some of the malignant diseases. In the early asbestos epidemiologic literature you saw tremendous rates for asbestos as compared to lung cancer and mesothelioma, and as the levels go down I think you are going to see more of the malignant disease as compared to fibrotic disease.

10 Q. I take it that's one of the reasons in the most recent document, tab twelve, that you suggest that lung cancer...that the author suggests lung cancer is the outcome that one should look at?

15 A. I think lung cancer is a very important indicator.

20 Q. Just one final question on this point I was pursuing before. The question that I was really trying to get at, is there a difference, in your judgement, in risk as between the situation wherein a worker is exposed to whatever dose you want, fifty fibers per c.c. over six months as opposed to over five years?

A. I think if you go with the idea that asbestos induces cancer through the irritation mechanism, the more you are exposed to that irritant, the greater your chances.

25 However, with the case of mesothelioma, we are not able to determine that. We know that people that have very short exposures can develop the disease many years later. I did not think the epidemiologic literature is really able to answer that question, but if you are talking about cancer being a result, in asbestos, of the insult of the fiber on the tissue over a long period of time, it's the same as radiation or anything else -  
30 the more intense and the longer you have the exposure, the greater your chance of developing the disease.



A. (cont'd.) That's about the best way one could answer that.

5 Q. I note that your document, in fact both your documents speak to the question of engineering controls and work practices, and are those issues to which NIOSH directs itself in respect of a particular substance and the recommendation as to a standard?

10 A. One of the criticisms that NIOSH has received since its beginning has been that we have not done very much work in the area of engineering controls or in the engineering control technology field as a whole. Our Institute has a division now that has been developed to deal with control technology issues, and I can assure you that in future documents, criteria documents, that come out, we will make recommendations in the area of control technology.

15 We would hope to work very closely with the industry in developing these recommendations. We, obviously, are not going to come out with, we would hope, recommendations that would be impractical to implement. We would request from industry and labour both to have a strong input into the area of control technology, and hopefully when we decide to develop a standard and develop a recommendation for a standard, we will be able to co-ordinate the research in our Institute to have an ongoing control technology project at the same time, to put into the standard.

25 With the area of asbestos, the best we have been able to do in the area of engineering controls and control technology is to relate our observations which have been made through the various field studies, and health hazard evaluations that have been done.

30 We know that one engineering control is, in many places, the application of wetting the material, which will reduce the number of dust and fibers that get into the air.



5 A. (cont'd.) There are some problems that industry tells us about that. In some applications it's not something that they can do. But these are observations and at the present time we are trying to include those observations in our recommendations.

MR. LASKIN: I believe Dr. Uffen has a question.

DR. UFFEN: I would like to summarize this, and you tell me if you've got it right.

10 At present, the standard is based on the lowest detectable, but in the light of the new investigations of engineering controls you might introduce the concept of lowest conceivable, and the regulation might be based on that?

THE WITNESS: I think that's a decision for the Department of Labour to make, but I think clearly that that could be the case.

15 MR. LASKIN: Q. Does NIOSH as an institute make its services available to manufacturing operations, or whatever, to design appropriate engineering controls or suggest appropriate work practices?

20 THE WITNESS: A. Under the original reading of the Occupational Safety and Health Act there was a health hazard evaluation and a technical assistance program set up in our Institute. The history of that program has been traditionally that it is utilized by the labour movement - the labour unions and the workers.

25 We have, and are intending to, and have tried to encourage industries to come to us to work in technical assistance situations where we can develop an ongoing working relationship.

30 One of the most recent examples of that has been in the area of pattern makers in major automobile industries. All three of the major automobile industries have come to us and asked us to assist them in assessing the cancer problem that they feel may exist in their industry.

I think that we, at least it's my feeling and this





5 A. (cont'd.) is not always...I can't speak for the Institute policy, but it's certainly my feeling that our Institute should be doing more of that, working with all organizations in trying to develop these from using the knowledge that we have plus the knowledge that the industry clearly have about their process that we cannot have because we are not working with it on a day-to-day basis.

10 So we do have that mechanism in our law, and I would hope to see in the future that it is utilized a lot more.

Again, it's not a regulatory mechanism. It has no regulatory implications to it.

15 Q. You are not...you wouldn't be going in there in any monitoring or inspection sense? You are going in to try to ...

A. Well, from the clear sense of the definition, NIOSH does not do inspections. NIOSH does monitor, it does evaluations in the workplace based at resolving problems and determining if there are problems, but we do not do inspections as such from a regulatory point of view.

20 Q. In terms of work practices and engineering controls, if I could just pursue it for a moment, are you suggesting that rather than proposing general practices or general controls that it is your view that it would be preferable to fit those controls to the particular work situation you are dealing with? That is, to tailormake the controls or the practices to the operation that you've got?

25 A. What may be a feasible control for one segment of the industry as compared to another segment of the industry might vary, and I think that we need to make general recommendations in the area of control technology, but that we need to work with the industry in implementing those control technology applications, and I certainly see that each individual situation may differ.

30 We can and we do have the ability to make general



5 A. (cont'd.) recommendations, but we can't go in and design an industry's process flow. Certainly that is going to be altered by the type of product they make, but we can make general suggestions.

Q. Can I ask you about one specific work practice or control, the respirator. Has NIOSH taken a position or made any recommendations with respect to the use of the respirator?

10 A. The respirator issue is one that has come, in the United States, very much to the forefront with the new administration at OSHA. NIOSH has been doing respirator research for many, many years, and I can make some general statements. I cannot make statements, nor will I make statements that institute our Institute's policy, but I will say that we have advocated in our past publications that the use of a respirator as a control  
15 mechanism is not something that you would want to use solely for control of worker exposure, that it should be used in application of control technology, engineering control and work practices.

20 First of all, we have found in our research that the respirators are not always as effective as one would hope that they would be. We have gone through a great deal of controversy very recently with various respirators being protective to the degree that the manufacturer has indicated that they are protective, and in different utilizations...for example, in  
25 firefighters using some of our respirators that are approved for general industry, they are not as effective as they would be in firefighting situations, as compared to a general industrial situation.

30 We know that respirators, when placed upon people, without appropriate medical evaluation, who have existing cardiopulmonary conditions, that these conditions can be exacerbated and that we can find many problems resulting from slapping a respirator on a person that has already existing lung





5 A. (cont'd.) disease. So we feel that respirators should be used as interim measures, and I say 'we feel' again. I want to clarify that. That's what we have recommended in the past. I cannot say what we will recommend under a new director in the future.

10 We feel in the past that the respirator is used in conjunction with other control procedures, but not as something that the worker would be required to wear for an eight hour day, five days a week, forty hours a week. That it should be something that is an interim measure until appropriate engineering controls and work practices can be initiated to protect the worker without the use of the respirator.

15 Q. I note in your latest document you also speak to the question of medical surveillance, and one of your recommendations was against...if I have read it correctly... against an annual examination.

Can you comment on that?

20 A. Again, I will speak as chairman of the committee that made the recommendation and not as a qualified physician to make those recommendations. We did evaluate and we received outside counsel on what we should do as far as medical recommendations

25 We felt that for workers...and it doesn't say all of this in the document, but I'll add a little bit to it...we felt for workers that had just come into the industry that a base line chest x-ray would be advisable, but to repeat that x-ray every year was not advisable. We were probably potentially doing more damage in x-ray exposure than the asbestos exposure, so we had kind of gradated this to recommend that for the first... that an x-ray be given every five years for the first fifteen years and then every two years thereafter, and that was the general consensus of the committee.

30 We felt also that a yearly examination of pulmonary function and chest examination should be given, but that the use of the x-ray on a yearly basis for those workers



A. (cont'd.) just coming into the industry, other than for the base line reading, and then five years subsequently was the advice that we would give.

5 We also indicated that we felt that the routine use of sputum cytology should be individually evaluated by the companies that were doing the medical screening, and that sputum cytology, while it was important as a diagnostic tool, was not necessarily a real good screening technique.

10 So we have somewhat backed away from the Institute's position of some years ago, recommending sputum cytology, and feel that that should be utilized as a diagnostic technique, but not as a screening technique.

15 Q. As I just heard you when you talked about the frequency of examinations, you dealt with workers who have just come into the industry and you draw a distinction between those workers and workers who have already been there for some period of time?

20 A. Maybe I wasn't...if a worker came into the industry brand new, had never worked in asbestos or in a dusty trade, then we would suggest that the routine chest x-rays not be given except every five years.

For those workers that have worked in the industry fifteen, twenty, thirty years, or in another dusty trade, we would recommend that you give the chest x-ray every two years.

25 Q. Have you looked at the question of the effect of removal of persons exposed to asbestos and with some evidence of fibrosis...removal from the workplace...and what effect that may or may not have in the future course of disease?

30 A. I can't answer that with any real authority, other than to tell you we don't think that the fibrosis will... we certainly don't think, and we know, that fibrosis will not reverse itself once a person has left the industry. It may not progress if adequate treatment can be given, but it's not going to reverse and get better.





5 A. (cont'd.) It's not like what we know about cigarette smoking, that once an individual stops smoking that the lung tissue will eventually get back to normal. Once you have inhaled the fiber, you are going to retain fibers in your lungs for a great period of time.

10 We do know that the concentration, at least some indications would lead us to believe that the concentration in the lungs may decrease over time as the clearance mechanisms take it and put it in the bloodstream and deposit it, maybe, in the lymph nodes or you excrete the material, but we have no indication to believe at the present time that the disease itself would reverse itself. We have nothing in the area of cancer to indicate that the risk is reduced once you leave the industry, other than just general principles that if you are not exposed to an irritant, your chances probably go lower .

15 But from epidemiologic evidence I'm not aware that we have that information to make that statement at the present time.

DR. MUSTARD: Can I...?

MR. LASKIN: Sure, yes.

20 DR. MUSTARD: When you are talking about cancers in the lung, that's one situation. What about the gastrointestinal tract, where the fibers may not stay around, and problems with cancer in that area? Is there any evidence that if you are withdrawn from the industry that changes?

25 THE WITNESS: I don't know the evidence on gastrointestinal cancer, that if you are withdrawn that the disease decreases. We have seen in some of the animal experiments now where we know that the fiber will penetrate the lining of the gut and get into the peritoneal area. But as far as removal from the intestinal area, I'm sure that there is greater removal there than what appears to be in the lung, but I don't have any statistics or any epidemiologic studies that I can quote that shows that the risk decreases the longer you are away from the industry.

30





MR. LASKIN: Q. Do I take it that NIOSH, in its criteria documents at least, has not made any recommendations with respect to removal of workers from the workplace?

5 THE WITNESS: A. You mean medical protection removal?

Q. Yes.

A. I'm trying to think. We did not make that recommendation in this.

10 Q. Was that a deliberate decision?

A. No, not necessarily. We didn't...I think you are probably referring to the lead decision where you have medical removal policies. We did not get into that. To a degree, we made some very general statements about lead and I think we talk about the committee recognizes that OSHA's recent lead standard contains a multiple physician review and mechanisms, whereas workers can get independent...the lead standard also contains medical removal protection programs whereby workers can obtain special health protection when necessary, accompanied by appropriate economic protection.

15 The committee felt that these programs were relevant to asbestos workers and that they should be considered by the Department of Labour when they develop their standard, but we did not make specific guidelines for that, and left the door somewhat open with OSHA. If they decided to do that, then we'll develop those.

20 We didn't feel at the time we really had a need to develop those recommendations for this particular document.

25 Q. You spoke a few minutes ago about the fibers in the lung, and I'm wondering whether from your own knowledge or from the research work at NIOSH you have looked at the question of correlation, if any, between fibers in the lung tissue and risk of disease, that whole area?

30 A. We are looking at that in our laboratories, and



5 A. (cont'd.) you had asked me somewhat earlier to recommend individuals in our Institute that would be people that could witness to, or talk to you about that, and I think Dr. David Groth, who was a member of this committee, who is a pathologist, is the person in our Institute doing that research, and I would defer those kind of questions to him and request that if you want to go into more detail about that, that you bring Dr. Groth here to talk about those types of questions.

10 Q. Fair enough. You also indicate at the very end of tab two, on page 94, that your recommended standard was not designed for the population at large, and any extrapolation beyond general occupational exposure is not warranted.

15 Can I ask you to comment on that statement, and let me just say by way of comparison that we have had witnesses who have come before us who have suggested the only way that one can ultimately achieve an environmental standard is to extrapolate from occupational studies.

Could you perhaps expand on your recommendation that you have made?

20 A. Okay. The recommendation that we made is based upon a couple of presumptions. One is that we are talking about a worker that is exposed five days a week, forty hours a week, time-weighted average of eight hours. In the general environmental setting, people were exposed twenty-four hours a day, seven days a week. Applying an occupational standard to a general environment would be probably a level that could not be necessarily tolerated in the general environment.

25 We feel that the occupational exposures are really the most intense exposures in most cases. There are some areas in the environment where you have very intense exposures, but if you see disease occurring in occupational settings, these can be used as indicators that disease can occur in the general environment, but I think the factor in the general environment,

30





5 A. (cont'd.) the level should be probably very much lower than what we would set for an occupational standard simply because of the duration of time a worker is exposed as compared to the person that lives in the general environment.

10 One thing that needed to be considered in setting occupational standards, and we have indicated this, are the hobbies of individuals. Sometimes what they do away from the workplace can be as important to a development of a disease as indeed just the exposure within the workplace. So I think there is a multitude of things that need to be taken into account, and to simply take the level that we recommend in the workplace and say this is what the environment level should be would be an overestimate, and we should lower that level probably in most cases.

15 Q. Can you just expand on the last comment you made about the hobbies of the workers as being a factor? What sorts of things are you referring to?

20 A. Well, we know that certain hobbies increase persons' risks to different types of diseases. If a person goes home from the factor and his hobby is to remodel cars, and he welds and he polishes and he sands and he changes the brake lining and does a lot of different things, then he is going to continue exposure to certain toxic chemicals away from the workplace.

25 We know that people who do gardening obtain exposure to pesticides. I think disease cannot be purely controlled by one factor alone. We have the responsibility for making sure that the occupational environment is clean, and our philosophy is that when a person comes out on the street, that when he goes into his occupation he should not be at any greater risk in his occupation than if he were on the street. That's the basis we make our standard recommendations for.

30 But we also have to<sup>be</sup>/realistic, to recognize that there are environmental factors as well as hobbies and personal



A. (cont'd.) factors that cause the person to be at risk.

5 But our prime concern is to make sure that that occupational environment does not put him at any greater risk than if he didn't work at that occupation, and that's what our recommendations are based upon.

10 Q. So that while you are aware of, realistically, these environmental and other factors, I take it from what you just said that they don't actually form a constituent of the ultimate recommendation?

15 A. No, but I think from a realistic point of view that you have to indicate to the worker in your educational programs...certainly we tell the worker that they shouldn't smoke. That's a stand that we all would tend to agree with, that cigarette smoking increases the risk of lung cancer.

20 We also need to educate the workers that there are other problems out there that can increase the risk to disease, and I think that we should be aware of those, particularly when we do epidemiologic studies and we interpret our findings. We should be aware of these other factors.

25 Q. Can I ask you just one final question on the environment, although I appreciate the focus of your Institute, but I noticed in the summary and the review of the literature that you did at least direct some attention to some of the studies which had looked at exposures in buildings, in the environment.

30 Is your Institute looking at any of those questions? As for example, the measurement of exposures in the environment, and conversion of fibers to nanograms, and as to whether that kind of conversion is possible?

A. Some of our purely research functions have looked into these effects. We have not incorporated those into any of our recommendations, obviously, but it's something that we have looked at in our Institute.



Q. On the particular question as to whether there is any appropriate conversion for measurement in fibers to measurement in nanograms, do you have any professional judgement on that question?

A. I do not, at this point.

Q. Can I turn away from your criteria document for a moment to one other of the papers that you have in here, and it's tab number three, of which you are a co-author, which deals with Mortality Patterns Among Hardrock Gold Miners, which is a subject of some interest to this Commission because, while we don't have any...or at least very limited pure asbestos mining in this province, we do have a considerable amount of mining of other types, and I wonder if in a general overview you could speak to this question in this article and perhaps give us some idea of what your results were?

A. To somewhat set the stage, we wanted to look at this particular operation. It had been something that our Salt Lake City office, when we had a Salt Lake City office in NIOSH several years ago, had been looking at - hardrock miners and metal miners throughout the United States. We had an indication that they had very low exposure to asbestos within this particular mine, so we decided that we would go ahead and do a mortality study on this particular mine.

We looked at those workers in the mine that would be at most exposure, predominantly those that were underground miners, and...I would have to go to the table, but I think, as you can see, we saw that there was some excess of respiratory malignancies that occurred in those miners.

Q. You are now at table...?

A. I am now at table one.

Q. Table one on page 338?

A. Right.

We did see some indication which we could not





A. (cnt'd.) explain by any other reason. It could be due to the low exposure to asbestos, and I think we made that statement fairly clear in the text of the document.

5 We have subsequently reanalyzed this data through a contractor with the Standard Research Institute, and their final report is being sent to us at the present time. I do not know what they have found, but they have expanded this cohort to look at a much larger segment of the population, both underground and topside people, and comparing the different disease rates.

10 We have done fairly extensive environmental monitoring, and the person that did that environmental monitoring is John Dement, who would be the appropriate person to tell you about the results there.

15 But just as a general overview on that paper, I would say that the indications at the time we did this study were that the exposures in the mine being to asbestos, and the result that we saw, linked the two to diseases occurring in that mine at very low exposures to asbestos, for which we had no other explanations.

20 Q. Just come back for a moment. This was a gold mine and what you are looking at was a form of an asbestiform which was in the amphibole series?

A. That's correct. That's correct.

25 Q. Is this kind of phenomenon likely to be prevalent? I don't mean the excess risk, but the existence of that asbestiform in other types of mining operations?

30 A. One of the things that we have found in looking at putting together our recommendation to MSHA for mining, is that in almost all mining situations you have a multitude of exposures to a variety of different materials. While you may be mining gold, you may be going through ore series that have other types of ore available. In this particular case you are going through an ore series that had an amphibole type or an



5 A. (cont'd.) asbestos type fiber occurring, and in other mining situations you may have this occurring, and you may not have it occurring. It depends upon the geographical location, the type of ore series that you are going through, but we have to keep this aware in mining situations.

10 While for us developing a standard for asbestos in mines in the United States, if we were to apply it only to those mines which mine asbestos, we would be dealing with less than a hundred workers. But when we are dealing with total miners in the United States, we are dealing with about five hundred thousand miners and many have potential for exposure going through ore series that contain fibrous material, and that's what we are looking at. We have been pursuing the idea of looking at a total fiber standard as compared to an asbestos standard in the mining, but we have not come up with any decision on that right now.

15 Q. I take it you tried to give some estimate as to what the concentration was, or what the exposure was in this mining situation. Is that...I'm looking at page 340 in the third last paragraph...and is the figure, the average concentration of point two five fibers per c.c., is that the estimate that you thought might be prevalent in the mines in the past, even though it was made in 1974?

20 A. Here again, the person that did these estimates was John Dement, who can answer it better, but the answer to your question is yes. He can give you more detail about it.

25 Q. He, I take it, by training is an industrial hygienist?

30 A. John is an industrial hygienist and epidemiologist. He has a masters in industrial hygiene and a doctorate in epidemiology.

Q. As you know, we have issued an invitation to





Q. (cont'd.) him, and perhaps you can use your persuasive efforts to prevail upon him to come.

5 DR. UFFEN: Counsel, there are a couple of questions that I might ask, and it won't take much time now.

MR. LASKIN: Yes, I would be delighted, Dr. Uffen.

10 DR. UFFEN: I was curious when I read this, why you were so careful to specify people who had never mined underground. A minute ago I think you said, I heard you say, that the current study is going to include some fellows who worked topside, too.

Why did you specify underground? Many asbestos mines are open pit.

15 THE WITNESS: Again, this was a gold mine situation where their exposures were occurring underground. We are not talking about a general mining situation. We are talking about one particular mine. Those people being topside would not have the exposure to the fibers because they were not going down into the mine the same as those that were working underground. They may have exposures, but we have limited our study to just  
20 the areas that we had measured, that being underground.

We are not talking about general mining statements.

25 DR. UFFEN: But does it mean that if they had ever worked elsewhere, that if they had worked in an open pit mine they could have been included, but if they had worked underground somewhere else, they would have been excluded?

THE WITNESS: We are talking about miners that worked underground at this particular mine.

30 DR. UFFEN: And without taking into account their previous history? Miners move around.

THE WITNESS: Right, I understand that. That is one thing that is often very difficult to ascertain from employment



THE WITNESS: (cont'd.) history records.

We limited this original study to those who worked underground in this particular mining situation, and we were unable to get adequate records on every one of those as to whether they had had experience underground in other mines.

I accept that as a criticism.

DR. UFFEN: This is a very important paper, from my point of view, because there aren't very many papers on that subject. The implications to the rest of the mining community as counsel has already pointed out, and your own express purpose here is to see is it some kind of a background level that we can use as a standard elsewhere, so I found it quite interesting.

Maybe I looked into it in more detail than was appropriate for today, but I would like to ask you another question which other people here will recognize because I have raised it before. I'm referring to page 337 of tab three, the second paragraph from the bottom, where it is referring to the death certificates: "Death certificates were obtained for those known to be dead, and causes of death were interpreted and classified by a qualified nosologist"...

Boy, I'm learning new words every day.

..."according to the revision of the International Lists of Disease and Causes of Death."

Now, the point is, were those death certificates altered, changed? What does 'interpreted' mean?

THE WITNESS: Okay. Let me explain to you a little bit of the process. In the United States, death certificates are classified or signed off by a physician in some cases, in some cases by a person who is not a physician, and they are sent to the local state health departments. Statistics are compiled on a state-by-state basis. We have fifty different sets of statistics.



THE WITNESS: (cont'd.) These are then fed into various other national reporting systems, but when we obtain a death certificate, we have what is written on that death certificate from the various states that we receive the certificates from, and to standardize that classification we have hired nosologists.

A nosologist is a person that is expert in the classification of disease, based upon the World Health Organization's International Classification of Diseases.

It's a real mouthful, but I don't know the derivation of the word nosologist, but the mortality statistics for the United States are compiled by the National Center for Health Statistics, and they use nosologists the same way, to assign a number from this classification system.

So we aren't comparing apples or oranges. If we would take the individual interpretation of what was a nosologist's interpretation of each of the individual fifty states, we would have a basket of fifty different apples, as compared to our comparison population, which was one apple.

So we have gone and reclassified all of the death certificates, using one nosologist who is familiar with that classification system. It's not necessarily an alteration. We certainly didn't change what was written down as cause of death, but their interpretation of what was the cause of death and the underlying cause of death may be somewhat different than what the nosologist classified in the individual state. In most cases, that doesn't alter it at all.

The other reason to use that is to have a nosologist bring it into one single classification system so that we are not comparing the fifth, sixth, seventh, eighth, different classification systems and we are just using one comparison. So we compare the seventh revision to the seventh revision, and that's the reason the nosologist is coding the certificate that





THE WITNESS: (cont'd.) way, and I think it's a fairly standard procedure that is fairly accepted throughout the world as a legitimate way to do epidemiology.

5 DR. UFFEN: But the thing that I'm finding a little bit puzzling, various people who have come before us I've put this similar question...how many times, or what percentage of the death certificates would need to be reinterpreted and altered? I've had everything from zero to thirty percent.

10 THE WITNESS: Well, I can't give you any better estimates. I can simply say that in certain states, and not picking on any one individual state, but in Kentucky you may have a county coroner that spells heart H A R T. We have very good examples of that occurring on death certificates, and he has had no medical training whatsoever. The guy dropped over dead and he saw no other reason except that he died of a heart attack.

15 Those are problems in the classification system and I think they are well recognized problems by most epidemiologists, that we can control for the best available way that we can. There are very few of those, but they do occur.

20 We, in our studies, try to follow up every death certificate by getting a pathology report and the medical record, if one exists, at the hospital, so that we have a little bit broader knowledge than just the certificate itself to make our judgement. But in comparing for statistical purposes, we have to base it upon what the death certificate interpretation is. We can't alter it and say this is what the pathology report says, because the national statistics do not do that.

25 So it's not a precise sytem, but it's the best system we have.

DR. UFFEN: May I pursue my...?

MR. LASKIN: Oh, please.

30 DR. UFFEN: Sometimes they are relevant questions. You refer quite frequently in this paper to



DR. UFFEN: (cont'd.) other kinds of dust and free silica. What do you mean by free silica?

I don't want to go around thinking...

5 THE WITNESS: Just a very simple answer. That's just another word for silica. It's the silica that...

DR. UFFEN: Is it silica or is it silicon dioxide? I can't imagine free silica floating around. I can imagine lots of silicon dioxide floating around.

10 THE WITNESS: I think it's the type of silica. Again, I'm not the expert that can give you the final answer on that, so I would rather defer that.

DR. UFFEN: There's another one which maybe counsel wanted to do another way. There's a paragraph in here about...

MR. LASKIN: Please pursue it, Dr. Uffen.

15 DR. UFFEN: Shall I?

MR. LASKIN: Sure.

DR. DUPRE: Please do, Dr. Uffen.

DR. UFFEN: Well, a great deal hinges here on the fact of, you know, the smoking once again. I'm trying to find that paragraph where it's dealt with in here.

20 Oh, yes. Page 342, the middle of the page, "The role of cigarette smoking also must be taken into account".

25 Now, in many of the presentations that have been put in front of us, there have been about three pages of tables pointing out how the conclusions were arrived at. I find only the one paragraph which says, in essence: you can't blame the smoking, you've got to blame the asbestos.

30 THE WITNESS: Well, one of the problems with doing retrospective studies, and I'm sure that the other people who testified before your committee have told you, is obtaining accurate smoking histories twenty years ago, fifteen years ago, ten years ago, etc.





5 THE WITNESS: (cont'd.) We have indications to believe that people who worked underground, because of the confined spaces and because of the other gases that are in mines, tend to not smoke while they are underground, as compared to those miners who work aboveground who can smoke all day long. The best judgement we can make is what we made in our statement, that we have no reason to believe that they smoked more, and as a matter of fact they smoked less, in our judgement, than did other individual comparison populations, and the smoking issue is always one that is going to be a nagging issue in any retrospective epidemiologic study.

10 But had we information to indicate that they smoked excessively compared to the reference population, I don't think we could have made this statement.

15 DR. UFFEN: The reference population was from other miners? The reference, I guess, here is to other miners. Is that a good reference?

THE WITNESS: The reference, we talked about the...

DR. UFFEN: They are all smoking too much.

20 THE WITNESS: That's true. I can't say too much about that. I think one of the things that has been lacking in epidemiology and one of the things that we are trying to develop in our Institute, is a reference population of controlling for smoking as best we can, and also controlling for occupation as best we can. But just because we can't go back twenty, thirty years and get adequate smoking histories, I don't think that you can do much with that other than to make the simple statement that we made, that our indications are that the underground miners smoked less than the aboveground miners, and that was the statement we made.

25  
30 DR. UFFEN: The conclusion of this paper, was it accepted in the epidemiological community, or was it regarded as a controversial paper?



THE WITNESS: Well, I...any epidemiologic study is generally regarded as a controversial publication, but I will say that this one was certainly regarded as an extremely  
5 controversial paper and that is one reason that we have independently gone back and had a contractor expand the study and redo the study, and we may see some different results.

But with the information we had available at the time, I think methodologically we have shown that we went the correct way. But it was controversial, so there is no way of  
10 stating that it was not.

MR. LASKIN: Q. Can you tell us, was there a particular reason why this mine was chosen and...or would this mine typify the kinds of exposures you might get in a number of mining situations, or was there something unusual about this  
15 mine that caused you to choose it?

THE WITNESS: A. Well, the unusual factor was that we had already been studying this under the silicosis survey that had been done, and we had information available that we could readily attach to, and we didn't have other agents that were in the mine that were readily known to be carcinogenic,  
20 so we were able to utilize this...and we knew that the asbestos-type material did exist in the mine, and that's why we chose it.

Had we gone out from scratch having no knowledge of this mine or any other mine, would we have selected this as being representative? I might point out that nowhere did we say  
25 this was necessarily representative.

The main point we were looking at was exposure to fibers less than...exposures to less than two fibers in a situation that we had some fairly detailed industrial hygiene data on.

Q. Just one final question before lunch. Do you  
30 have any judgement as to whether one might expect to see, with any



Q. (cont'd.) degree of frequency, this kind of exposure in other mining situations?

5 A. The indications that we have from our data that we have been reviewing, of the silicosis survey and other studies, would indicate that there are many other mining situations where you have low level asbestos-like fiber concentrations occurring in the mines. I don't have information on the health affects, however.

10 MR. LASKIN: It might be an appropriate time, Mr. Chairman...I think I am virtually finished my list of questions, but I'll review them over the lunch hour and I'll chat with my friends about the timetable.

DR. DUPRE: A very good time, counsel.

The Commission then will rise until two-fifteen.

15 THE INQUIRY RECESSED

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THE INQUIRY RESUMED

DR. DUPRE: Very well, counsel.

20 MR. LASKIN: Q. I just have one further question or two and it relates to something, Dr. Lemen, that we talked about very early on in your testimony, and that was NIOSH's approach to controlling the workplace by looking at in industry rather than by looking at individual substances, and I'm just wondering, you have indicated you haven't done anything in  
25 practice with respect to an industry where asbestos is prevalent, but could you, by way of example, tell us about an industry where you have adopted that approach and the kinds of things you are looking at and what you do?

30 THE WITNESS: A. I would like to...it's somewhat of a, not necessarily a new approach, but again somewhat of a logical approach, that we are not going to abandon completely looking at substance-per-substance, but we are also living in a





5 THE WITNESS: A. (cont'd.) time where we know that substances don't occur just randomly separate, that we can tease out in the environment, and I think a good example of that is the petrochemical industry where we have some indication that there may be an excess of brain cancer, that leukemia may be in excess, and that other cancers may be in excess. But to try and go into that industry and to sort out one chemical that is causing those health effects is, from an epidemiologic point of view, a nightmare. To go and look at each chemical individually to see what the effects are may not be realistic, because we know that in some chemical situations where, for example, if you had hydrogen chloride and you have formaldehyde that occur together, that you have generate BIS (chloromethyl) ether, which is a very toxic and carcinogenic chemical.

15 I think that we have an interest in encouraging as much as possible the beginning of looking at the mixtures as they occur in the workplace, and what are the effects of mixtures and process flow, and where the cancers are occurring it may be much more important to know the occupation of the worker and where he is at in the process flow, and then to look at the combination of chemicals that occur because any one of them separately may not cause that cancer, but it may be a combination. It could well be one of them, but I think that modern industry is becoming so sophisticated, and the chemical industry is certainly the area that we've spent a majority of our monies on in our Institute in the last few years, looking at health effects, and I feel that if we can start looking more at process and the total environment within the plant, from a public health point of view, we may be in a much better situation than just regulating one chemical, one effect.

30 It's going to be something that's hard to do, because the data are not really prevalent right now on mixtures. I think that we need to start trying to rethink our research potential and



A. (cont'd.) our research dollars to promote looking at the mixtures and the different processes as being the real areas where we should concentrate our efforts.

5 Q. So in respect of asbestos, is one of the things that you will be looking at the ways in which asbestos may react with other substances in a particular work environment?

10 A. I would say that in the area of asbestos it's a little bit different. I'm more directing my comments toward the chemical environment, but certainly other exposures that occur in the asbestos industry are very important, and they can't be just laid aside. When we look at it, we should look at the different types of industry. The textile industry, obviously, is somewhat different than the friction industry, and etc.

15 Asbestos, unfortunately, is not a good example of the combination of different chemicals, as it's easily seen in the chemical industry. But there are some variety of substances used in that industry which should be considered also.

20 Q. Why isn't it a good example? Because it hasn't been shown yet to react synergistically with anything other than tobacco?

A. That's one of the basic reasons. And often times asbestos is not mixed with a lot of other real toxic materials. In some cases it is, but in some cases it's not.

Q. But in any event, I take it that is an area that you will be looking at in respect of asbestos?

25 A. We feel that it's important to look at the total work environment. The traditional industrial hygiene approach in the past has been to look at individual substances, and the reasoning being that it's much easier if you have a number to start developing engineering controls to control for.

30 But I think that we can't live in that type of situation. We need to look at the real world situation where it's a multitude of exposures.





MR. LASKIN: Dr. Lemen, thank you very much. You have been extremely helpful to this Commission.

Thank you, Mr. Chairman.

DR. DUPRE: Counsel.

M. Bazin?

CROSS-EXAMINATION BY M. BAZIN

Q. Dr. Lemen, referring to the study under tab three, which is the gold miners study, and which you qualified yourself this morning as being extremely controversial, you mentioned that this was being redone, was it?

A. About four...I can't give you the exact date, but several years ago, the then director of our Institute, Dr. Jack Finkley, made a decision to take that cohort and to go out on contract. The contractor that was selected was the Stanford Research Institute, to not only...not to reanalyze our study, but to expand on it and to look at some more parameters, and particularly to get a larger cohort, including surface as well as underground mining, and also to develop more in-depth environmental measurements where possible.

And that study is the one I was referring to that is being sent to us as a completed study now.

Q. You said it was given out on contract to what...?

A. Stanford Research Institute, which is located in San Francisco.

Q. And that was done three or four years ago?

A. That is correct. They have been working on it since that point in time.

Q. Originally this investigation was carried out by NIOSH and NIOSH people, is that correct?

A. The original study was all NIOSH people.

Q. There is reference on page 340, of an investigation by MESA. Could you clarify what role MESA played



5 Q. (cont'd.) in this investigation, or what did they refer...what does MESA...what investigation did MESA carry out in this context?

A. Just let me refer to the reference first.

Q. Yes. Page 340.

10 A. That was not necessarily a study, as I understand it, and here again forgive me, this has been four or five years ago since I have really gone into depth in this study. But MESA was the predecessor organization to MSHA, which is now the Mining Safety and Health Administration.

15 The information that appears in this study were the result of environment samples taken by the Mine Enforcement and Safety Administration, I think was the accurate name at that point in time, and those samples were included in our array of samples that have been collected in that mine.

They were taken into consideration in our analysis, the environmental samples.

Q. But NIOSH was taking its own samples?

A. Yes, they were.

20 Q. Aside from what MESA may have given to NIOSH, is that correct?

A. That's correct.

25 Q. You are aware that one of the coauthors, Mr. Dement, has made statements about the fiber concentrations in that gold mine after this report came out? Are you aware that Dr. Dement made some comments about the dust concentrations?

30 A. There is another paper that appeared in the same New York Academy of Science proceedings as this. That was, I think Dement was senior author, Zumwalde, I don't remember, and maybe Wallingford was the third author, and it goes into more depth on the particular measurements taken.

Q. Always on the same gold mine?



A. That's all in the same gold mine, that's correct.

5 Q. That they found up to eleven micrograms per meter of arsenic, as compared to what is mentioned in this report as being point zero one five? On page 340.

10 A. Again, the connection between this study and that study, when the samples were taken at the same time, I do not feel at liberty to tell you...or not liberty, I don't feel adequate to tell you what the differences were, because I did not take the samples, I was not in the mine.

15 John Dement was, and if he testifies before the Commission he may be able to clarify any inaccuracies that may appear between the two reports, but it's my understanding in talking to John that there are not inaccuracies between the two reports.

I think that it may have dealt with where the samples were taken in the mines, but again, I qualify my answer saying that from a firsthand knowledge, that is not an area that I can comment on.

20 Q. Well, let me go through...you authored this report, correct?

A. I was a coauthor on this report.

Q. A coauthor on this report?

A. As a matter of fact, the third author on the report.

25 Q. Therefore, you are aware of what is to be found in this report?

30 A. Again, I will indicate that the approach that NIOSH has taken in the past has been a team approach. We have several authors on many of our reports, the primary author takes responsibility for the entire study. My particular input into this study was in the analysis of the life table, and I was not





A. (cont'd.) involved in the analysis of the environmental samples.

5 Q. How could you explain from your experience and the role that you have played in NIOSH, a difference between what is called at page 340, the highest single concentration at two point eight fibers, and Mr. Dement's findings of concentrations up to four fibers?

10 A. Again, I did not take the environmental samples, but it's my understanding that the measurements that Dr. Dement is talking about in the second paper, as compared to the first paper, relate to the area within the mine where the samples were taken, and that accounts for what was going on.

15 Also, I believe that samples were taken by Mr. Dement after this paper was published, and they may well refer to those samples that were taken subsequent to the publication of this paper.

Q. That comment would apply to everything surrounding the sampling of the dust measurements, is that your testimony?

20 A. I don't think I understand exactly what you are saying.

Q. The length of the fiber, the percentage of more than five micron fibers found, all of this aspect of the report?

25 A. To the best of my knowledge, the samples that are reported in the paper that is exhibit three, or number three in our exhibits, were all the samples that were available to John Dement, who was the industrial hygienist on this first paper, at the time this paper was presented for publication.

30 The second paper that he wrote, I cannot comment on, but I would make the presumption that it may have included samples taken after this paper was prepared.

Q. The problem with your original report, table



Q. (cont'd.) three, that needed more investigation, would that be in the area of measurements, amongst other things?

5 A. We certainly felt at the time that this report was prepared that there was need to have more environmental measurements taken in the mine, and we made that very clear in our oral presentation as well as the written presentation.

10 Q. Coming back in that report on page 337, just a question of clarification, on the question of death certificates that were obtained and subsequently interpreted by a nosologist, qualified nosologist, who was that person?

15 A. The qualified nosologist in this case was Miss Marian Hyde, who is a fairly well recognized nosologist who is currently employed with the National Cancer Institute, the epidemiology activity, working for Dr. Joseph Fraumeni.

At the time that she did this study, she was working for NIOSH and had been involved in the development of the ICD codes for the World Health Organization, and had...I'm not sure how many years...but over twenty years experience in the area of nosology.

20 Q. At the time she was working for NIOSH?

A. That's correct.

Q. On the...and talking about the type of fiber found here, we are only talking, I believe, about amosite?

A. And cummingtonite-grunerite ore series.

25 Q. Excuse me?

A. You cannot talk about amosite in this situation, because amosite is the name that's given to a certain fiber that is mined in South Africa. The fiber is similar to amosite, but not amosite per se.

Q. Which is grunerite?

30 A. Cummingtonite-grunerite is the ore series that we were looking at.





Q. Which is comparable to the amosite...?

A. Somewhat comparable, yes. But as you well know, amosite is only given to a particular fiber that is mined in a particular geographic area of South Africa.

Q. On your testimony concerning NIOSH and its role, you referred to the research aspect of the role of NIOSH, and the reports that...or the criteria documents, I guess you call them, that are given to OSHA and/or MSHA, is that correct?

A. The criteria documents are developed either by personnel within our Institute, or through contract with contractors to our Institute. These criteria documents are then reviewed by NIOSH, and transmitted to the Department of Labour, either MSHA or OSHA.

Q. When you say they were reviewed, it's an internal review?

A. No. We have an external review process as well as an internal review process. If you look at most of the criteria documents, we list and we can give you who the reviewers are. In many cases we select who we feel are the most qualified people in the field, and we try and get a representative sample from industry, academia, the labour movement, etc., and we try to do that consistently with each of the documents we develop.

Q. Are these the same people that you have referred to as peer group when you've talked about tab twelve of exhibit twenty-six, which is the latest assessment of...that was filed this morning?

A. They may not be the same individual people, but we would use the same selection criteria. This is being reviewed at the present time by peer groups within the Institute, and we are selecting groups outside the Institute to look at this document. You just happen to have been given a copy prior to a lot of people outside the Institute getting it.

Q. So as of today the review that you were talking



Q. (cont'd.) about was an internal review?

5 A. As of today the review that I'm talking about has not been completed internally or externally. The paper represents the opinions of the three authors, and not the Institute. We are in the process of doing our review and making a determination what it will represent, but I thought in clarity that while it did exist in our Institute and you could get it under the Freedom of Information, that I should just go ahead and give it at this hearing, and I gave it for that reason.

10 Q. Have you determined yet, without having sent it out, which groups will be reviewing this document in due course?

A. I have not made a final decision on that yet.

Q. There is no final decision?

15 A. I would be open for suggestions from you. I'm sure that the Asbestos Information Association will receive a copy, and Johns-Manville will receive a copy and probably Raybestos, to name just a few.

Q. This report was made internally by three people, at your request?

A. That's correct.

20 Q. That's correct. Did you request this report in writing, or how did you request this?

A. How did I request that they do this report?

Q. Yes.

25 A. Our Institute has a series of, I think, five major divisions and three offices. I am in charge of two of the major divisions in our Institute, the Division of Technical Services as well as the Division of Criteria Documentation and Standards Development, and when I transmitted the information to these people to do a report, each of the three people work for me and I requested them to do a report on asbestos. I did not put in writing, I simply instructed them orally what I wanted, and would like their independent assessment. I purposely did not  
30



5 A. (cont'd.) get involved in the preparation of this report because I wanted them to come to me with an independent assessment of what they saw in the literature.

Q. So the instructions to these three people that report to you or work for you, were given verbally?

A. That's correct.

10 Q. Am I correct in assuming that the request was to examine more specifically documentation about chrysotile asbestos?

A. The report was to look at the relationship of health risk to chrysotile in a mining situation, primarily, and...

Q. Why did Mr. Dement's report find its way into that?

15 A. They brought the Dement report in because of its single look at the chrysotile area, and when you read the report I think you will see that it is treated separately from the three mining reports.

Q. Is it treated separately in the conclusions?

A. The conclusions are general conclusions.

20 Q. They are general conclusions?

A. That's correct.

Q. Including what may have been assessed from Mr. Dement's...

25 A. That is correct. And I think once you have had a chance to read it, you will see how they developed the arguments to come up with those conclusions.

Q. So the request was made to these three people to look at the health effect of chrysotile in the mines, and subsequently one or the three people came back to you and said we must also look at this one? Is that what happened? The Dement one, I'm talking about.

30 A. The three people talked to various people...I cannot tell you who they talked to...in the development of this





A. (cont'd.) report. I presume that they talked to John Dement, and asked him...

Q. Why would they talk to him?

A. Well, he worked in our Institute.

Q. Is he still working there?

A. Until the end of this month, yes.

And they had talked to other people to get suggestions as to what appropriate papers would be most appropriate to use in this analysis, and I'm sure that he said that he had just completed his report and that it dealt with chrysotile, and that they felt it would be appropriate for them to make comment on it. And that is probably why it is in there.

Q. Even if it dealt with the textile industry and not a mine?

A. That's correct. But, again, I'm saying that this information was to look at chrysotile, in particular, with mining as a subarea to look at.

Q. At the time, Mr. Dement was working for NIOSH?

A. That's correct. Mr. Dement has worked for NIOSH for ten years.

Q. After internal review and outside review, this report is to be dealt...how will you deal with this report?

A. After we have the appropriate review, this report will be incorporated into any criteria documents that we may develop, and the appropriate portions dealing with mining would be incorporated into the mining criteria document, and it may even be published at some point in time in a peer review journal after the report is completed and received the peer review from within and outside the Institute.

Q. It's directed, I understand, to the Mine Safety Health arm of where your reports end up, is that correct?

A. This report is not directed to them. The criteria document we are developing will be directed to them.



Q. In the criteria document, this document would be?

5 A. I'm not saying that the entire document would be in that. We will get professional opinions about the validity of the findings that are presented in this document, and we will then make an Institute decision as to what we will put in our criteria for recommendation to MSHA.

10 Q. Could it be that the textile aspect of this report would be deleted so that only the mines aspect of it would find their way into the criteria document.

15 A. It could well be, but if there are important pieces of information such as we have already put into the general industry criteria document information on mining, I don't see why it wouldn't be inappropriate...or why it wouldn't be appropriate to leave, if we have good information on textile and it relates to a particular type of fiber found in the mine, to at least reference that in the document.

But certainly for regulation purposes you would deal with the mining situation.

20 Q. Wouldn't you think that Mr. Dement's report speaks for itself and doesn't...having been working for NIOSH, doesn't need interpretation by three other NIOSH workers?

A. I think all reports always need to have peer review. I think that Mr. Dement's report, as well as anyone else's, needs peer review.

25 Q. In the context of an examination of the chrysotile effect in mines?

A. Yes.

Q. I didn't have time to look at it in detail over lunch...

30 A. I would be very happy to make Dr. Alavanja available to this Commission if you feel that you would like to have him come up to talk about this report.





5 Q. The question that I wanted to ask was, is it your opinion that this report could be split in two? In other words, one section to cover what appears to be the original intent, and that is to look at the mining area as compared to the textile area?

10 A. I think that any report can be split just about any way you want to split the report. We made a decision, the authors of this made a decision that they would include this information because it dealt with chrysotile, and that's why it's in the report. It may well be that we would change it later.

Go ahead.

15 Q. You offered to us this morning the timetable on this report..

A. Not this report. On the criteria document we developed.

20 Q. I'm sorry. On the criteria document. Could you give us a ballpark time schedule for...

A. The overall time frame that we are talking about now is some time in the fall of next year.

25 Q. Some time in the fall of next year?

A. Yes. However, there are mitigating circumstances recently, with the new naming of an Institute director, and with the geographical relocation of the division that's doing that. That certainly is going to have some play in the time frame, so that may have to be altered because of the people being moved, and the Institute may take some different stand.

30 Q. The peer groups would be consulted some time next summer?

A. When the report is completed, the peer groups will be consulted. It does not mean, however, that we will not pick up the telephone or that we will not go and visit people outside our Institute to get reaction to certain comments that we would be putting into the document, which we have done all along.



5 A. (cont'd.) We try to, when we start developing a document, to get the concerned industry, as well as the concerned labour movement group, involved at the beginning of the document development so that we can have input in selecting the plants that we may use in making our evaluations, etc.

10 So we try to keep the interested parties involved from the beginning of the document. Right now, we are formulating who in NIOSH will have responsibility for the different sections of the document.

15 For example, the toxicology section as compared to the epidemiology.

Q. You mentioned that NIOSH had made a hundred and seven standard recommendations. In what time frame were these recommendations made?

15 A. NIOSH began in 1970, the first criteria document that was published. I believe, but I may not be correct, but it was the asbestos criteria document. I believe it was either asbestos or carbon monoxide, in 1971, late 1971.

20 So those hundred-and-some documents have been developed since 1971.

Q. And have covered a whole...

20 A. They have covered a gamut of things such as carbon monoxide, benzene, tungsten...

Q. Minerals and chemicals?

A. Yes...fibers.

25 Q. You mentioned that twelve or fourteen had been regulated, is that correct?

A. That's correct...if you include some of the fourteen carcinogens that were regulated in one group...regulation on fourteen carcinogens...several years ago.

Q. Within the same package?

30 A. Those regulations, I might add, are not all in effect now. Many have been pulled back and changed over the



A. (cont'd.) past...

Q. After publications in the federal register by the various...by OSHA or by other agencies?

A. I don't follow your question.

Q. You said that they were pulled back.

A. OSHA has withdrawn some of the regulations that they put into standards, that we made recommendations on.

Q. On the question of the animal studies that have been carried out in connection with asbestos, you mentioned that this was a way of analyzing the measurement techniques?

A. I don't know that I said it exactly that way.

Q. That's why my note indicates. That's why...

A. What I am saying in concern to animal experimentation, as compared to epidemiologic experimentation, is that you are able to have controls in animal experimentation that you are not afforded in epidemiologic investigations.

For example, in animal experiments you can control dose. You can control exposure time. You can control diet. You can control a multitude of factors that, in the general population of the work force, you have no control over.

You can control for smoking in animals, you can either have them smoke or not smoke.

Q. I understand. But in connection with the measurement techniques, is it my note which is not clear, or did you...

A. I would have to <sup>go</sup> back to the record to see exactly what I said, but I don't believe that I would indicate that it was measurement technique. You do have the ability to know exactly what you have dosed the animal with, and that's the point that I was trying to make.

Q. Just for the record, am I correct in saying that the two fiber level was adopted in 1976?

A. The two fiber level was adopted in 1976, but





A. (cont'd.) recommended earlier.

Q. Recommended by NIOSH earlier?

5 A. That's correct. But it was adopted by law in 1976...I think July, 1976, to be exact.

MR. WARREN: It became effective.

THE WITNESS: Became effective. It was adopted earlier, I'm sorry.

10 M. BAZIN: Q. It had followed a criteria document that had been forwarded to NIOSH...from NIOSH to OSHA?

THE WITNESS: A. Forwarded from NIOSH, that's correct.

M. BAZIN: No further questions.

MR. LASKIN: Linda?

15 CROSS-EXAMINATION BY MISS JOLLEY

Q. I just have a few questions, and the first question is concerning your study of the friction workers with Joe Wagoner and John Dement, I think it was...no, Cynthia Robinson, later.

20 Is it my understanding in some of the other materials that we have read, that have been submitted under your name, that in fact it was a Dutch-Amish population where these workers were taken from?

A. In that particular area of Pennsylvania there was a large Amish community.

25 Q. Right.

A. Some people had made speculation that the Amish community's smoking habits and personal habits may have some effect. We have tried to validate that and have not really made any validation that there was a large number of Dutch-Amish people working in that plant. That was a speculation made by 30 other people that had read the report where we indicated that that part of the country was predominated by Dutch-Amish.



Q. Right. I think that's where I was confused, is I read the comments on that.

5 A. We were trying to give somewhat of a geographical characteristic of the people that were living in that particular area.

10 Q. Right. In both tab number one and number six, and this is of concern to this Commission, you had a significant increase of death from corpulmonale and congestive heart failure, and I think this is an interesting...I think the Commission, and I'm sure the Chairman of the Commission will probably raise questions, but it deals with the nexus of other diseases and asbestosis...deaths from other diseases and asbestosis.

15 A. I think that maybe Dr. Frazier, and certainly... can certainly give you a better physiological explanation, but with existing cardiopulmonary diseases, you oftentimes get a right-sided heart failure which is called corpulmonale. It's more or less a consequence of pulmonary disease, and so oftentimes it is a competing factor with the asbestosis. The death certificate may well classify the person dying of corpulmonale, and indeed they probably had a fibrotic lung disease, but it was not classified as the cause of death. The corpulmonale was classified as the cause of death.

20 So the two diseases are quite related. Corpulmonale, I must say, is not only related to asbestosis, it's related to other pulmonary diseases.

25 Q. Similarly, congestive heart failure?

30 A. You can have a variety of problems, and congestive heart failure could well be a diagnosis on the death certificate that could be mistaken, sometimes, for corpulmonale, etc. We tried, to the best of our ability, to get pathology reports and most cases of congestive heart failure could have been misdiagnosed as corpulmonale. Oftentimes that can occur.

Q. Do situations...I know that you took out





Q. (cont'd.) bronchitis and pneumonia. Were there situations where people with asbestosis would in fact die of pneumonia?

5 A. Sure. I think that it's very reasonable to know, or to assume that people can die of other causes. For example, if a person has an existing pulmonary condition, their susceptibility to developing pneumonia or other respiratory diseases may then be greater than a person that doesn't have that existing disease, so pneumonia could very well be a cause  
10 of death in an asbestotic person.

Q. I think we are pursuing it for reasons of compensation, and that's of interest.

MISS JOLLEY: Dr. Dupre, do you want to pursue any of this?

15 DR. DUPRE: Thank you for the invitation, Miss Jolley.

On that table, indeed on that article, the one thing that struck me as different from any other tables or compendia that I have seen so far, was your data on suicide. I noticed that the specific point that you make on this on page  
20 137. Of course, I notice that this paper was published in 1979, but on page 137, you point out that, "At present, an association between suicide and pre-existing asbestos-related disease cannot be ruled out. However, continuing investigations are examining medical records and coroners' reports for further..." etc.

25 Have these continuing investigations yielded anything?

THE WITNESS: We are continuing the investigation. Unfortunately, I was really one of the people that was pursuing this most readily, and a year ago I was put into a new  
30 assignment which has taken most of my time and made it very hard for me to continue this. I am trying to get back into



5 THE WITNESS: (cont'd.) looking at this in more detail. I think it's very important to note that this is one report on suicides. We have done extensive literature searches trying to find other reports in the world's literature dealing with suicides, not only with asbestos, but other occupational exposures.

10 We have found some reports dealing with suicide, but it is a unique finding that has only been reported with association to ...in an asbestos study. I won't even go so far as to say association with asbestos....but in an asbestos study and our report.

15 Again, I must caution everyone that it's one finding, but it does deserve further analysis, and it was such a striking excess that we felt that we really had to put it into the report as a finding, and that is where it stands today.

DR. DUPRE: Dr. Mustard?

20 MR. MUSTARD: Can I just add to this nexus question? This is one of the few documents that we have seen where the subject of lymphoma or lymphosarcoma is raised. I thought I would like to ask you the question...table eight, page 140, of tab six...are you aware of other studies that have the same difference? You expected three point two eight deaths, whereas you actually had seven of lymphoma and lymphosarcoma.

Are there other studies that show this?

25 THE WITNESS: I think that at the beginning of the paragraph, where it says "several reports have suggested a possible association", that being the Kagan, which is a Russian study, and the Gerber, and the Jan Lieben study, we certainly have some indication that other reports do have some excess of lymphoma.

30 We have made no real speculation, other than to speculate that in ridding the lung and other parts of the body of the fiber, that the lymphomas develop in the lymph nodes, being clogged up with some of the fibers, and that this may account



THE WITNESS: (cnt'd.) for some of the degree of lymphoma that is occurring. But the reports are not a great number. There are a few reports, but that's about where we are.

5 DR. MUSTARD: Well, let me ask you a very direct question. Obviously, by the wording of that, you directed your study to try to make sure that you got that information through this study, I would suspect. Is one of the reasons, therefore, why, for example, it doesn't appear in some of the other studies is because the epidemiologist didn't try to extract that  
10 information?

THE WITNESS: I should explain to you that the type of epidemiology that NIOSH does, the type of epidemiology a lot of people do, is to look at all causes of death.

15 If we had directed our study to look at what we knew about asbestos - that being lung cancer, mesothelioma, asbestosis - and not generated information on other causes of death, this finding would have gone completely unnoticed.

We do analyze for every cause of death. When we do a study, we do not let one death category slip out. We analyze for each of the various death categories, and that's  
20 how come this finding appears here.

DR. MUSTARD: Let me just put it in a slightly different way. Epidemiologists are human, like everybody else, and therefore being aware of the death certificates problems... that physicians are badly trained to code the deaths, they want to get the death certificates filled and away from it, and they  
25 put down whatever comes to their mind at two o'clock in the morning, they don't worry about these lovely classifications...knowing the softness of that problem, which I apologize to the engineering profession for our inadequacies...there is a problem there, and when you go into death classifications in epidemiological work, of course areas which have been signalled to you from the past  
30 as being important areas, you may try a little bit harder to





5 DR. MUSTARD: (cont'd.) clean up the data that is coming in in the other areas, and you may be one of the few outfits which is strict across the line, and if so I have a bunch of students I would like to send down there from my place.

Is there not a bit of that at risk in the system, that indeed the targetting of the cleaning up of the data...I mean they are going to record all the deaths, but the cleanliness of it in terms of your assessment may be emphasized in some areas more than in others?

10 THE WITNESS: I think a general statement on epidemiology is warranted, and that is that the real value of epidemiology does not lie in one individual study.

15 If you have one study that has an overwhelming excess, you may be able to put a lot of reliability upon the finding. But when you have the real value, we see in epidemiology, is the consistency in findings. The more information you can report in a particular study, the more important that is.

20 So if we see ten studies being consistently showing an excess of say lymphoma or lung cancer, that's much more important a finding than one study showing an excess of lymphoma, and which you point out as being a fallacy or a problem with epidemiology, it certainly is a problem with epidemiology and one of the inaccuracies that we have to live with.

25 We try to control for this in various other ways, sometimes by doing case control studies within general retrospective studies, etc., but it is a problem and it's one that I alluded to this morning in the different filling out of death certificates.

It's one that we try to control for as best we can, and the best way we can control for it is that our reference population suffers from the same problem.

30 DR. MUSTARD: Can I just say one more thing about the lymphoma and lymphosarcoma question.

MISS JOLLEY: Please.



5 DR. MUSTARD: The diagnosis of lymphoma and lymphosarcoma is not as easy a diagnosis as some of the other parts, and the sophistication of this application, I would suspect, has not been uniform across the decades.

That poses a question in my mind. I suspect your safety in your assessment is that you hope that that's true for all the groups?

THE WITNESS: That's true.

10 DR. MUSTARD: But that is a limitation?

THE WITNESS: That is a limitation, that's correct.

DR. DUPRE: Miss Jolley, you very kindly...one more question before I hand it back to you. I promise I will.

MISS JOLLEY: Sure.

15 DR. DUPRE: It's just again when I looked at table two on page 135, that I try to go through my own course in either epidemiology, or maybe it's nosology at this point, I'm not sure which.

20 But when I look at the nonmalignant respiratory disease, to which Miss Jolley, indeed, was directing your attention a little earlier, and looking at the male table on page 135, where of course you find the big excess of observed over expected, the deficiency in influenza, pneumonia, etc., is other respiratory diseases.

25 Now, the question I have is simply born of the kind of semi-ignorance that you are in when you are in the middle of your first course in this, but a number of the papers that I have read will refer to deaths from asbestosis. Now, do I take it here that the other respiratory disease classes which are five ten to five twenty-seven...and of course I had never looked at...include one or more classes, but in a number of other studies that I have looked at they would be in a reported table as  
30 death from asbestosis?

THE WITNESS: One of the reasons to break it





THE WITNESS: (cont'd.) out this way is that if we use our comparison population, and in this particular study we used the United States population as our comparison population, we cannot really break it out much more refined.

In other words, we can't break out just asbestosis across the board for every year that we are dealing with, so we are really in a situation where we have to break it down in general categories and when we are dealing in a period from 1940 to 1976, it's about the finest breakdown we can put into it.

This includes other categories such as silicosis, etc., but we can say, as we do in our text, the number of cases within that seventy-six that were coded out as asbestosis, but for statistical purposes we can't compare one or the other.

DR. DUPRE: Miss Jolley, please.

MISS JOLLEY: Q. I would like to move on to measurement now, and I'm a little bit confused...I think we have had conflicting testimony before us about long versus short, wide versus thin or narrow, and from reading the materials the IARC, and the discussion in tab seven, it's my understanding that there is a general acceptance that the diameter is probably the biological problem of the fiber. Is that...?

THE WITNESS: A. Let me give you an answer that is somewhat based upon knowing that I might get this question thrown at me today...talking with Dave Groth, who is our pathologist, yesterday and asking him what his opinion was, so I'll try and paraphrase a little bit about his opinion.

Certainly the diameter or the width is an important factor. We believe that those that are generally less than three microns in diameter are very relevant to health, and the smaller the diameter, the more relevant they tend to be.

We also believe that as the length gets longer, that the likelihood of the fiber penetrating to the depth of the lung is lessened.



A. (cont'd.) We think that this primarily, almost completely disappears when you get up to a hundred microns in length.

5 So we are talking about a fiber width of below the three micron, in general, and a length of below the hundred, but the smaller the diameter and the less the length the deeper that it tends to get, from his reckoning, into the lung. As most of you well know, that asbestosis, when you are speaking of asbestosis, if you look at an x-ray, as compared to silicosis, you generally see the majority of fibrosis occurring in the lower lobes of the lung, as compared with silicosis which generally tends to manifest itself throughout the lung, but some predominance to the upper portions.

10 Q. The proposition, and perhaps I'm not presenting it fairly, was the whole issue of macrophage attempting to destroy a longer fiber, and the proposition presented to us, and I may be misrepresenting it, but was in fact that the longer fibers are more difficult for the macrophage for to destroy, and therefore the longer fibers are therefore somehow...

15 A. Certainly the smaller fibers are removed. The smaller the fiber, it can be removed by the macrophages and get into the lymph system or into the blood and be excreted. You tend to see in autopsy...and again I refer that to Dr. Groth...you tend to see these longer fibers that stay there, and oftentimes if you look at the ferruginous bodies you will see them with the fibers incompletely engulfed and sticking out, and sometimes they may even break after they have penetrated the lung.

20 Q. But there is no reason for us to believe that the measurement, the five microns in length measurement criteria by phase contrast is a technically feasible length to measure? It's not for health reasons, it is not based on the biological impact?



5 A. It's really a hard position that I've put myself in to say this, but the real problem is below the five micron. But it's our Institute's recommendation that we measure at the five micron length because of the feasibility of using the phase contrast microscope.

10 I certainly feel that there is a hazard below that, and I would in no way say that just by measuring just those fibers greater than five micron you have an accurate assessment of what is occurring in the industry, or what is safe for the individual to breathe.

Q. In fact, in some industries the percentage of the smaller fibers compared to those five micron fibers varies significantly, is that...?

15 A. In the situation that I'm most familiar with in Tyler, Texas, where we looked at a friction plant using predominantly amosite, and looking with the electron microscope, we found that over ninety percent of the fibers were indeed less than five micron in length.

MISS JOLLEY: Dr. Uffen?

20 DR. UFFEN: I hope you are not offended if I refer to you as counsel?

MISS JOLLEY: I'm not sure if I am or not.

DR. UFFEN: You have an uncanny knack of raising subjects that make us want to get into it.

25 I understood you to say a few minutes ago when we were talking about the dimensions, was answered by reference to Dr. Gross as the expert.

THE WITNESS: Groth. G R O T H. Not Gross. There's a big difference.

DR. UFFEN: Oh, Groth.

There's a lovely discussion due to a Dr. ...

30 THE WITNESS: Paul Gross.

DR. UFFEN: ...Paul Gross. Quite different.





DR. UFFEN: (cont'd.) Were you going to call this at all, or not?

MISS JOLLEY: No, you go ahead, Dr. Uffen.

DR. UFFEN: Because this is...

THE WITNESS: What are you referring to?

DR. UFFEN: Page 342 of tab seven, where Dr. Gross...in the paragraph in the middle of the page...

THE WITNESS: Gross.

DR. UFFEN: Gross...talks all about the chemical aspect and possible biological activity when minerals are cleaved.

I'm afraid I thought it was the same person, but I'm glad to be corrected.

Have you found..."as discussed at this meeting, cleavage plane development normally follows crystal face development in minerals. Yet cleavage may break chemical bonds so that cation species..." and I won't go on.

Then right at the end he said, "This area should be explored as rapidly as possible."

It seems to me to be the alternative to dimensions.

THE WITNESS: I think that you have hit upon an area that is certainly not my area of expertise, and I'll not attempt to really address it in too much detail. I think that Dr. Groth, and I heard from the committee that you might be asking Dr. Pooley to present, and Dr. Pooley is certainly more qualified to talk about this area than I am.

But it is an area that our laboratory people in our Institute are looking at. That's about the best that I can give you right now.

MISS JOLLEY: Q. I was going to pursue the next discussion on...this is probably unfair to ask you because it was in fact a presentation by Dr. Langer of Mount Sinai, so probably...but there was a discussion that perhaps crocidolite...



Q. (cont'd.) on page 343...that the actual fiber dimensions of crocidolite might make it more respirable, that that might somehow explain...

5 THE WITNESS: A. I think that some people have speculated this. From our experience, we cannot give you much more information that that, that it is a speculative argument at this point in time.

10 Q. In the case that you were discussing this morning with John about the...or Mr. Laskin...about the development of mesothelioma, and perhaps more mesothelioma developing from crocidolite, and I think that's the basis on which a number of people have composed a more stringent standard.

15 It is true, however, that in all of the chrysotile population there have in fact been mesotheliomas developed, in the chrysotile populations that you have studied?

A. In the chrysotile populations that we have studied, we have seen mesothelioma.

Q. Right. Right.

20 The next part of the whole issue of measurement that I wanted to talk about a little bit with you was the issue of time-weighted averages, and it's of some concern, first of all, whether you set the level that is considered safe or not, but that aside, we deal, in Ontario, with time-weighted averages over forty hour work week, and that's a very long time over which to be measuring and equalling out, and that kind of thing.

25 NIOSH, on the other hand, proposes an eight hour work day, and can you help us with why you would go to eight hours as opposed to forty, or whether that's better. or...?

30 A. I think that the eight hours probably affords a little bit better analysis of the worker, because often times you work segments of four or five eight-hour work periods, and sometimes you don't. There is a lot of variety in the work, and we felt, purely from a management point of view in managing the





5 A. (cont'd.) results that we obtained in our sampling, it would be better to average it out over the shorter period of time than the longer period of time, which may be somewhat misrepresentative because the longer period of time may include a movement to a variety of different operations, as compared to over an eight hour period there would be less movement, and that was one of the reasons.

10 Basically it had also been somewhat of a traditional way for us to develop TWA's in the United States.

Q. The last aspect is, does your asbestos standard apply to construction?

A. Our asbestos standard is supposed to, but there is a lot of controversy about construction versus general industry, and I don't think it's really a resolved issue.

15 Q. But it does in fact apply?

A. To my understanding, yes, it does apply to the construction worker as well, and OSHA has made visits to construction sites, using the same standard.

20 But I will say that there is a great deal of controversy in the United States that it should not, that there should be two different standards.

25 Q. Our standard setting agency, again, is exempting construction from a number of our standards. It worries me about construction in exactly how you...for instance, in the whole removal programs, does OSHA become involved...and again, it's unfair probably to ask you...in the enforcement of the standard setting situation in the removal of asbestos from schools, and things like that?

A. No.

Q. No?

30 A. Not to my knowledge. Maybe you have a better answer to that.

Q. Right. Right.



A. I think EPA is the responsible party.

OSHA could, I suppose, conceivably, under the new federal executive order where you had a federal school and teachers who were exposed get involved, but that would be the only case that I would know of.

Q. There was two short areas that I would like to pursue, and one of them was...Dr. Weill, when he was here, indicated...and we have asked other people...but, that in order to establish that lung cancer was associated with the asbestos exposure, one would also have to have asbestosis. I was wondering if you feel from your knowledge of the literature that that's necessary.

A. My feeling, from the knowledge of the literature, is that you do not necessarily have to have asbestosis to experience lung cancer. I believe that that was an early belief that some people, apparently Dr. Weill, still hold. But we, as an Institute, do not believe that is true, and have made that position known.

Q. In any of the...you mentioned this morning that in...that you get involved in perhaps presenting testimony about workmen's compensation, whereas you don't involved in the actual administration of compensation.

Have you ever suggested guidelines around the compensating of asbestos diseases? Guidelines that should be followed to determine whether the diseases are attributed to the asbestos exposure?

A. We have never made formal recommendations, to my knowledge.

Q. The last area that I would like to ask you about is the whole issue of smoking. That is, it's a difficult area for us, of course, but one of the propositions presented to this Commission is that probably one of the best ways to reduce the health hazard of asbestos is to choose only nonsmokers,



Q. (cont'd.) or to remove smokers from the population. While we would agree that there is a multiplicative effect, I'm wondering would that answer the question?

5 A. Let me make several comments on that, one comment being that certainly as a public health person I would recommend that people not smoke. Our Institute has recommended that people not smoke. However, we feel in our interpretation of the Occupational Safety and Health Act that we don't have authority to tell people to smoke or not to smoke, that our  
10 authority lies in making recommendations for providing a safe workplace no matter what the personal habits of an individual may be.

I personally believe, and I'm mixing personal with other, and I'm sorry for doing that, but I personally  
15 believe that you would cut down tremendously on the amount of lung cancer in this country if people did not smoke cigarettes... in your country as well as our country...and would encourage asbestos workers not to smoke.

I do not agree with the policy of employing only nonsmokers. That's my personal opinion.

20 I believe that the environment within the industry should be clean enough that people would be protected from at least the risk of the asbestos exposure, and they accept, as a personal habit and through a personal choice, the cigarette smoking. They don't necessarily have that same choice when they walk in off the street to have a job.

25 That reflects combined opinions. I'm sorry to put them together.

Q. We might have reduced illness. We would also have reduced revenues for the government here.

MISS JOLLEY: Thank you very much.

THE WITNESS: You are welcome.

30 DR. DUPRE: Thank you, Miss Jolley.





DR. DUPRE: (cont'd.) Mr. McNamee, do you wish to come out of the bullpen now?

MR. McNAMEE: Thank you.

5  
CROSS-EXAMINATION BY MR. McNAMEE

Q. In your study, tab number eight, it's really a transcript of testimony before a House of Representatives Subcommittee, I gather, on labour standards, you were present along with...I guess leading the team was a Dr. Robins from NIOSH? Is that correct?

A. He was the director of our Institute at that time.

Q. This is tab number nine, which appears to be a followup to that, is that correct?

A. That's correct.

Q. On tab number eight at page 67, I believe it's testimony by Dr. Robins, indicates there are three thousand present uses of asbestos. I would assume...is that three thousand uses at present, or over the course of history?

Surely some of these...just before...I just want to get an idea.

A. That's basically a quote that's been quoted in a variety of textbooks and books on asbestos, and I would make the presumption that it's three thousand uses over a period of history that asbestos has been put to, and I would be very hard pressed to give you the names of the three thousand.

Q. Well, is there any tabulation anywhere...not that I'm ever going to read it...but is there a tabulation?

A. I guess I would have to refer that to the manufacturers of the material.

Q. It's just that one of these hearings, at tab number eight, there is quite a bit of discussion about taking asbestos out of the environment, or at least removing



Q. (cont'd.) these uses and finding safe substitutes.

5 In reading this, I would gather that your position at NIOSH, and the people who testified, that there is very little, that progress is very slow in removing these various uses of asbestos and finding safe substitutes, is that correct?

10 A. I think the real concern that we have is that there are substitute materials in many cases, the relative toxicity of which have not been completely explored. We do know in the case of fibrous glass, that is substituted in some cases, that manufacturing a larger diameter fiber can probably eliminate many of the respiratory problems associated with that particular substitute.

15 But industry itself had told our Institute on various occasions that there are substitute materials. One industry in particular has indicated that in brake lining they are developing a substitute for the chrysotile which is being used in brake linings. We have cautioned in each case, and we don't know exactly what that substitute material is because it's apparently a protected, a trade secret of the company that made that indication to us, that the toxicity of that be thoroughly  
20 explored before using the substitute.

25 But we do recommend, where known substitutes exist, that we do substitute for nonasbestos material in the environment. We feel that that's an appropriate recommendation that not applies to asbestos, but other toxic agents, where we know of substitutes.

Q. I think you, yourself, in tab nine, at page 191, used the example of Burlington Industries abandoning the use of benzidine dyes. Is that another example?

A. Page which?

30 Q. Tab nine, page 191. I believe that's your testimony.





A. That's a true statement. I don't know if it's my testimony.

Q. Maybe that's Dr. Robins again, then.

A. It may well be Dr. Robins, but that's a true statement.

Q. Sorry, I went back and I'm sorry, I do have a statement by you somewhere here that I did wish to raise.

Sorry, did you wish to say something?

DR. DUPRE: Will you permit me to sneak in a question?

MR. MCNAMEE: Sure, go ahead.

DR. DUPRE: Following up something.

I was intrigued by your observations, Mr. Lemen, in your response to counsel here that in the whole question of the relative safety of substitute materials that the trade secret element, which is importance of course from the standpoint of the firm that is developing the substitute, complicates the matter.

Now, just in terms of your general experience, is this a greater complication in the domain of industrial material than it is in the domain of food and drugs?

THE WITNESS: I don't know. I really can't answer that question.

It certainly poses some problems to us in the industrial setting. Having never worked with food and drugs, I really have no knowledge of how relevant it is in that particular setting.

DR. DUPRE: Maybe Dr. Mustard will enlighten us?

DR. MUSTARD: I'm not in a position to enlighten, Mr. Chairman, but of trying to acquire further information along this line, if I may.

In this question of substitute substances, you say that there should be careful assessment of the potential of the substitutes. What kind of requirements have you proposed



DR. MUSTARD: (cont'd.) in NIOSH for this purpose, and if you have proposed them, what position do they hold within the regulatory structure of the United States?

5 THE WITNESS: To answer your question with the last part first, they hold no position because we are not a regulatory agency.

DR. MUSTARD: No, but I say within the regulatory structure of the United States? The EPA or anything like that.

10 THE WITNESS: The Toxic Substances Control Act is the closest thing to that, which requires that new substances being introduced in commerce be tested for certain degrees of toxicity, depending upon the knowledge that is available. There is kind of a scale for what should be done and what should not be done.

15 As far as substitute materials in industry, we have no real requirements on our regulations for fiber glass at the present time, or any of the other substitute materials. We simply are making that as a public health statement from our Institute, that we would encourage those responsible industries that are using substitutes, or proposing to use substitutes, to prior  
20 test those, at least animal test, to determine that their toxicity is not as great as that we already have with asbestos, because if we wait until those materials have been introduced and are broadly used, it's going to be twenty or thirty or forty years down the line before epidemiologic evidence would be  
25 suitable to tell us whether there is or is not a hazard.

DR. MUSTARD: Do you have a criteria document for this?

THE WITNESS: We have a criteria document on fibrous glass, yes.

DR. MUSTARD: But for testing all substitutes?

30 THE WITNESS: No.



MR. WARREN: Dr. Mustard, could I be helpful here? I don't want to testify, but maybe I could be helpful just on the law in the United States on this issue.

5 Just to follow up, not to say anything really inconsistent with what Dr. Lemen is saying, but with respect to any new substance, there must be a premanufacture notification given under section five of the Toxic Substances Control Act which was passed in 1976. That premanufacture notice is essentially that, a notification that you intend to market a substance. There are minimal disclosure of toxicological information...that which 10 you have, you have to disclose...but there is not a comprehensive testing regimen for new substances which go into commerce.

15 If that's helpful, I think what it's suggesting is that there is not, in the United States, as I think Dr. Lemen has likewise said, any comprehensive regimen which is comparable to a new drug application at FDA.

20 There, there is a much more extensive series of toxicological testing that has to be done for new chemicals. There is a notification requirement, and some minimal testing... it's a matter that's in dispute, how much...but nobody is contending that it's going to be anywhere near as extensive as the new drug application at the FDA, which involves an awful lot of pharmaceutical testing.

25 DR. MUSTARD: I suppose then, either one of you might answer this question...let us suppose I introduce a new substance to seal asbestos, and which is now going to go onto a structure of a school system. There is no requirement, I take it, in the United States, that this new substance is tested in terms of its potential health hazards down the line?

30 MR. WARREN: That's true. Let me continue another thought. The premanufacture notification requirement of section five of TOSCA applies to both new substances and new uses for existing substances, so that if you have a previously-used





5 MR. WARREN: (cont'd.) substance that you are going to use for this hypothetical purpose that you are referring to, that substance would fall under the premanufacture notice requirements of section five.

But, as I've said, the requirements to obtain clearance under that premanufacture notification system are essentially minimal as compared to the much more extensive system which we have for drugs.

10 I might add, one of the reasons why, this is more gloss, but one of the reasons why the system turned out to be different was that when the Toxic Substances Control Act was under consideration by Congress, there was fear that the prolonged periods for testing, which have become quite prolonged and quite expensive in the United States, would constitute a drag and an inhibition to the development of new chemicals.

15 So it's that kind of tradeoff which resulted in the essentially notification scheme which we have in the United States.

20 DR. MUSTARD: Okay. The second question comes specifically over to the thing that you are referring to: If I introduced a new fiber into the system, say for insulation purposes, and it's a new substance, I would file my notification...

MR. WARREN: Yeah.

25 DR. MUSTARD: ...under both jurisdictions, is that right? Would I have to do it in the labour as well as the...

MR. WARREN: No. TOSCA is under EPA, first of all...I guess, that's...

THE WITNESS You would not have to file anything with labour.

30 DR. MUSTARD: So that in a sense, a new substance in the labour side could get into the system and be found out twenty years down the road? There is no regulatory process to



DR. MUSTARD: (cont'd.) try to...

MR. WARREN: Well, there would be notification.

5 In other words, the Toxic Substances Control Act applies broadly to substances, and that includes minerals and everything you can think of, essentially, which is defined as a toxic substance, so that what you are postulating is a chemical fiber or some other kind of fiber which would go into commerce, and that would have to go through the notification scheme and presumably, since there is a lot of co-ordination among agencies, there would be  
10 a general awareness of...there would certainly be constructive notice of this having taken place, and if it became a significant item in commerce, which it might not, but if it did, I think these people would know about it, as would the other regulatory agencies.

15 DR. MUSTARD: But there would be no requirement that I would have had to screen my fiber in animal experiments to show that it did not cause mesothelioma and lung cancer?

MR. WARREN: Yes.

DR. MUSTARD: That requirement is not there?

MR. WARREN: That's not there.

20 DR. MUSTARD: Thank you.

THE WITNESS: There is one other aspect that keeps the federal regulatory agencies apprised of what the others are doing, and that was under the previous administration, I believe it was under - not prior to that - that a group called the Inter-regulatory Liaison Group was developed, and has  
25 representatives from each of the major regulatory agencies sitting on that group to review regulatory stances between the different agencies, and that's primarily the EPA, OSHA, Consumer Products Safety Administration, Food and Drug Administration, etc., and they all sit on the general council to review the relationship of one regulation to another. We sit on it as an exofficio type  
30 member to add input from a science point of view.





THE WITNESS: (cont'd.) So that's one way in the United States that we try and keep apprised of what the other agencies are doing.

5 MR. McNAMEE: Dr. Mustard anticipated many of my questions...in fact, more than I intended to ask, but...and much more intelligently.

MR. McNAMEE: Q. There are a couple of other questions on this particular point. In fact, I did find your testimony at page 72 of tab eight, and it was about the glass fiber.

10 You indicated that in fact the latency period, or that glass fiber or insulation hadn't been in use long enough to determine whether it posed certain risks for certain types of disease, is that correct?

15 THE WITNESS: A. The major use of glass fiber in the United States started around World War II. There was a pilot operation in one particular plant that used a small diameter fiber. The majority of fibers used were somewhat larger diameter, and the real commercial use of fibrous glass, to our knowledge, did not really start occurring until the early sixties, and the population size has really been insufficient to give us a latency period from a statistical point of view that is sufficient to show if there is or is not an excess.

20 We are in the process of looking at that one pilot operation of about three hundred and fifty employees, to follow them through time to see if there is any excess of lung cancer in that particular group, but the results are not complete today.

25 Q. Well, if I suggested to you that you, yourself, might very well be in a position where you might extrapolate from observations, just laymen's observations...you might say, well, asbestos, we've always known in asbestos that workers from, say the first year that they were exposed, through the first ten years, they were complaining about, you know, they didn't like to

30



5 Q. (cont'd.) work in this environment. Whereas...  
of course that might have been twenty years ago...but whatever,  
there were complaints right from the beginning, whereas now you  
have people working with glass fibers and there doesn't seem to be  
that basic, underlying complaint, you know, obviously complaints,  
and you are extrapolating from that to say that, look we have  
twenty years of experience and the workers are not complaining  
about, you know, shortness of breath and that, and therefore  
10 you...I suggest that you may be anticipating that you are going  
to find fewer mesotheliomas and other diseases.

A. I don't know which workers you are talking about,  
but we get a lot of complaints from fibrous glass workers as to  
health problems associated with fibrous glass, and the...I would  
not say that we are making any assumption like that.

15 The assumption that I am making is that if  
you manufacture a fiber glass particle that is greater than  
three or three point five microns in diameter, the likelihood of  
that particle getting into the respiratory tract is much less,  
and you may well eliminate the problem by manufacturing a process  
technique.

20 But I am not saying that there is no problem or  
that we anticipate a lesser problem with the fibrous glass industry.  
Where we have fibrous glass particles that are similar in size to  
asbestos particles that are in the respirable range, we may  
well have as equal a problem.

25 I think that the Stanton animal studies certainly  
showed that fibrous glass would induce the same types of cancers  
as did asbestos, so we are not ready to make some type of  
presumption such as that.

30 Q. Well, to go back, I misquoted you at page  
191 of tab nine. I believe it was Dr. Robins going on with this  
business about the duties of industry, and he states:

"We are working on the problem, but we strongly



Q. (cont'd.) "believe that is primarily the industry's responsibility to test and to know the hazards associated with each and every chemical, substance or process they use".

Now, do I understand...should I understand from that that industry should know in advance, or somehow should be able to give a reasonable prediction of the disease-causing...

A. Again, this is Dr. Robins' testimony, but I may add one comment, I think, that what he was trying to say here was that when industry uses a substance, they should be responsible in knowing that there are or are not health effects that could possibly be associated with the use of that substance.

For example, if industry is using beta-naphthylamine they should be well enough aware of the literature to know that beta-naphthylamine causes bladder cancer, and if they don't, if they are using another substance that they have no toxicological data on, he is implicating the need for industry to finance and fund testing to show whether the substance is indeed toxic or not toxic before it exposes workers to it. That that is a responsibility of the industry.

Q. Well, to get back to glass fibers, you at NIOSH really cannot predict without...until you have this experience...what the ultimate health effect would be. Are you suggesting that industry somehow have a higher duty?

A. We at NIOSH are in a position of assessing the animal studies and the human studies. We do think that industry should treat fibrous glass as a potential problem until they can show that it is not a problem, and we are simply putting a warning out, not saying that it is carcinogenic or not saying it's not carcinogenic, but saying that it should be treated prudently and that they should protect the workers to the same degree that they would protect the workers with asbestos, until we have the appropriate answers that we have in the area of asbestos today.





A. (cont'd.) That's merely a warning that we are recommending to the industry.

5 Q. To carry it one step further, suppose we have a use of asbestos that NIOSH thinks is dangerous or somehow should be disallowed, and no acceptable safe substitute is presently recommended. Are you recommending that we stick with the asbestos or stop that use of it and wait until you find an acceptable substitute?

10 Maybe that's too large a question.

A. Could you rephrase that again? For some reason I missed a part of what you were saying.

Q. Maybe I'll take the asbestos thing a little farther, and suppose we come to a position that...well, we have heard about the urea formaldehyde insulation...

15 A. Right.

Q. ...suppose we determine that also another insulating material like fiberglass is dangerous, and the insulation industry, or up in Canada where it's a little bit more important than down south, we say that we just can't come up with a substitute that's safe and what are we going to do, are we going to just leave our homes without insulation?

20 A. Again, I don't believe our Institute necessarily has an opinion that I could speak for, but from a personal point of view, we have never been in the position of wanting to drive industry out of business. If the health benefits have to be weighed against the substitution benefits, and if  
25 you were going to leave your home without insulation and without fireproofing, and there were no other substitutes, then the most appropriate action to take is to use the material but to treat and use it in a prudent manner so that workers and people who live in the houses are not exposed to it any greater than  
30 what you can do.

There are areas where you have to use materials



5 A. (cont'd.) that are toxic. We realize that. We are not advocating that every toxic material be removed from the environment. We know that they have to continue to use toxic materials.

We are simply saying when you have no substitute and you have to use a toxic material, use the most prudent and most efficient means of protecting workers, and the most efficient means of protecting people other than workers that may be exposed to it.

10 Q. Okay, to get onto to one other matter, and inasmuch as I represent the government in various forms, there is a workmen's compensation problem that maybe came up. It's in tab eight, and page 76, a Mr. Erlenborn, who I understand is a Congressman from Illinois, is that correct?

15 A. Which page again?

Q. That's page 76, tab eight. It has to do with x-rays and black lung disease.

A. Yes.

20 Q. Just to make a synopsis of this, it appears that Mr. Erlenborn was suggesting to you people that, from NIOSH, that there are a lot of claims being allowed for black lung disease that really were not supported by...well, he is suggesting down near the bottom, about two paragraphs from the bottom,

25 "In black lung, less than eight percent of people who have long-term exposure to coal dust are disabled, according to independent medical studies, and yet something in excess of sixty percent of those filing claims have the claims allowed and are given compensation. Would you say that there might be some abuse?"

30 I don't understand the background of all this and I'm just wondering how this particular point came up and if you have any comments on it?





5 A. First of all, let me disqualify myself from making any comments about coal miner's pneumoconiosis. The question was directed to Dr. Merchant, who is the director of our respiratory disease laboratory in Morgantown, who deals with the coal miners pneumoconiosis, the black lung. I have not had any experience with coal miners pneumoconiosis, nor do I know anything about the percentage of cases that are true versus the ones that are not true. I cannot comment on that. Nor did I attempt to in this testimony.

10 Q. In tab twelve, exhibit twenty-six, which is a study done by Michael Alvanja, Christine New and Judy Parsells, your page two conclusions states:

15 "3. Lung cancer mortality is the most useful outcome variable on which we can base a mortality risk assessment for chrysotile miners and millers".

I believe that same conclusion appears in exhibit twenty-six somewhere, tab twelve.

20 Do I understand from that that, say, you examined fifty thousand chrysotile miners, if such a cohort exists, and you found, say, five thousand lung cancer cases, that you could somehow use that to determine the mesothelioma expectancy or other rare type cancers?

25 A. No, that's not at all what that's saying. It's simply saying that lung cancer is the disease entity upon which the assessment of risk was based. It doesn't say that you could use lung cancer to predict how much asbestosis or mesothelioma occurs. It's simply just the one finding in this particular group of studies that had sufficient numbers to base some risk assessment on.

30 Q. Okay. Because this led to another question, and I'm not...I haven't sat down with somebody who has explained to me in full how these various epidemiological studies are done, but from the evidence so far, I indicate that trying to follow up



Q. (cont'd.) the majority or a large percentage of the cohort group is quite important in this type of study, is that correct?

5 A. Yes. We feel very strongly that the more people you can follow, the greater the accuracy of the study. It's a simple matter of the more numbers you have, the more validity you can generally give to the findings.

10 Q. Well, I can see this for certain rare diseases. Let's take an example that you have five hundred asbestos workers in a textile plant, and you follow only two hundred and fifty. In the two hundred and fifty that you can't follow there might be one or two mesothelioma cases that you might miss.

15 However, if you had a cohort, a study group of a hundred thousand and you could track fifty thousand, and when it gets into that type of number I don't see the necessity of following up the other fifty percent, especially if the fifty thousand was well representative of the original hundred thousand.

20 A. I think if the fifty thousand represented a random sample of the hundred and fifty thousand, that's a different question.

Q. Okay. Well, then, it's more likely that fifty thousand will be closer, fifty thousand out of a hundred thousand, that you can follow will be closer to a random sample than say, two hundred out of four hundred?

25 A. Depending upon the...whether the fifty thousand indeed represent a random sample as compared to the two hundred and fifty.

30 Q. Okay. Well, just to follow that. Supposing you followed the hundred thousand, what you are saying is, we follow the hundred thousand, if we select twenty-five thousand at random out of the hundred thousand, we are probably going to get markedly similar results. Is that correct?



A. We may, and we may not.

5 I think that I might refer a lot of your questions to Dr. Chase, who is a statistician. I am not a statistician primarily by training, but I think that the points that you are making are some of the basic principals that are behind statistics.

Q. Then there is a possibility of somebody that I can examine on this?

A. Yes.

10 Q. There is? Okay, I'll not pursue it too much further because I was kind of interested in it.

A. I think the points that you bring up are relevant.

15 Q. Okay. I have only one other basic...in answer to Mr. Laskin's questions, I think you have recommended this point one fiber per cubic centimeter, and that one fiber is longer than five microns and three-to-one ratio, is that correct?

A. That's correct.

20 Q. Then he asked you, and he used the figures, and I don't know how many zeros he dropped in there, but he went about point zero zero zero one fiber, something like that. I think it was at least three...like, one - ten thousandth?

A. I believe that's correct.

25 Q. Did I understand your answer that if that was...if it was practical...I'm sorry..I think your answer assumed that it could be detected by phase contrast microscopy, is that correct?

A. No.

Q. Maybe you would clarify it?

30 A. I think his question to me, and correct me if I'm wrong, you are the one that asked the question...was, if the phase contrast microscope could measure down to point zero zero zero one, would NIOSH make that recommendation for a standard.





5 A. (cont'd.) I said, based upon the philosophy that we had in making this recommendation, yes we would make that recommendation, but we in no way indicated that the phase contrast microscope has that capability.

As a matter of fact, I can pretty much say categorically it does not have that capability.

MR. LASKIN: You expressed the purpose of my question much better than I could.

10 MR. McNAMEE: Q. After I heard that, I then read back to you tab two, and you were dealing with ambient air levels. I don't pretend to be an expert, but I thought that maybe that point zero zero zero one might be even less than the ambient air levels, and page 77, maybe you could interpret this, it says: "In summary, ambient asbestos levels, as determined

15 by electron microscopy techniques, are generally less than ten nanograms per cubic meter, with occasional peaks as high as a hundred nanograms per cubic meter".

I think that was testified to already, and certain studies done in cities.

20 DR. DUPRE: Excuse me, counsel. That's page 77, what tab?

MR. McNAMEE: Page 77, tab two.

DR. DUPRE: Tab two.

25 MR. McNAMEE: Q. To go on: "Only a few studies of ambient levels have been performed using phase contrast optical mircoscopy. These studies indicate ambient levels to be generally less than point zero one fibers greater than five microns per c.c., with some peak values as high as point zero three fibers greater than five microns."

30 Maybe I misunderstood that, but that would appear to me that if you read this thing , if you could read down to a low level like



Q. (cont'd.) point zero zero zero one, that might be less than the ambient environment, and you would recommend that?

That might be a simplification.

A. Okay, that's a very good point. I think that in the workplace it's a very controversial issue to say that we know a substance is toxic, we know that the ambient environment carries a level at a certain level, such as you are talking about here, where is that ambient level coming from? It might well be coming from escaping emissions from the industrial environment.

If we know that it's toxic and we know that it's toxic down to that level, we could still very theoretically go and ask for a work place standard to be lower than what your ambient level would be in the general population, which would in turn probably reduce the ambient level in the general population.

MR. McNAMEE: Fine. Thank you very much.

DR. DUPRE: Thank you, Mr. McNamee.

Is this an appropriate moment to take a break?

MR. LASKIN: I think it is, Mr. Chairman, give our witness a little respite.

DR. DUPRE: Okay.

THE INQUIRY RECESSED

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THE INQUIRY RESUMED

DR. DUPRE: Counsel, proceed please.

MR. WARREN: Dr. Lemen, let me clear the air before we begin. Those remarks that you made about doctors from the State of Kentucky this morning, I hope didn't intend to apply to lawyers as well?

THE WITNESS: No. I wasn't really talking about the doctors in Kentucky.





MR. WARREN: No, I hope not.

THE WITNESS: I should have picked my home state of Missouri, because it suffers from the same type of problem.

MR. WARREN: Another thing maybe we ought to clear up. We've all been calling you Dr. Lemen today.

THE WITNESS: I'm mister.

MR. WARREN: It's true, I think, that you are working on your Ph.D., but don't have it?

THE WITNESS: That's correct.

MR. WARREN: I guess in anticipation of your success, I'll continue to call you doctor, but you don't have it yet?

THE WITNESS: That's correct.

MR. WARREN: When do you anticipate that you will?

THE WITNESS: Well, if I would have had time to write my dissertation instead of taking this new job, I may have had it by now, but I've kind of put it on the back burner for the present time, feeling that the more important thing is to continue my research and my career.

CROSS-EXAMINATION BY MR. WARREN

Q. Now, a number of times this morning you have talked about, and this afternoon, you talked about your function, what you can say and what you can't say in your testimony here today. It's fair to summarize, I guess, that you are not here to express the policy of NIOSH or of its new director?

A. No, I'm not.

Q. I guess the same applies for OSHA?

A. I'm certainly not talking about the policy of OSHA. I can tell you in my remarks what our policy has been in the past, but with a new director coming on, it's quite obvious that that policy can change.

Q. I guess the same also applies to the MESA...



5 Q. (cont'd.) I keep calling it the old name, but the recommendation which we have been talking about here today. I take it you can't, and are not prepared to predict, what the recommendation which will eventually result from NIOSH is likely to be?

A. No, I cannot.

Q. With respect to the tab twelve, is it...

MR. LASKIN: It is, Mr. Warren.

10 Q. Likewise, I don't think you...you don't want to predict how that study is going to look in its final version, either because of policy input from the director or scientific input within the agency or outside the agency?

A. That is correct.

15 Q. In 1976, we had a new criteria document for asbestos, and during the four ensuing years there was no action taken on that recommendation?

A. That is true.

Q. And no action has been taken on the 1980 recommendation either?

20 A. That is true.

Q. I guess from what you were saying this morning, it's true that NIOSH has made lots of recommendations over the years and very frequently...in fact in the majority of cases...no action has been taken on those recommendations?

A. That is true.

25 Q. If I read your criteria document correctly, it seems to be premised on the following three elements, and correct me if I'm wrong. They are that asbestos is a carcinogen, both in animal studies and in epidemiological studies; it's also a substance which produces pulmonary fibrosis; it's a carcinogen, and secondly, in your judgement, or the agency's judgement at the time, there was no safe level for exposure to  
30 a carcinogen in the sense that there was always going to be some



5 Q. (cont'd.) incremental risk at any level; and third, that you therefore would...in the case of asbestos... take that standard down to the level which is the lowest detectable level?

A. The first two statements are correct. I think the third statement talked about the lowest feasible level, and that would be the only correction I would make on it.

Q. Right.

10 In the case of asbestos, the lowest feasible ends up translating to lowest detectable, in that criteria document. Is that a fair statement?

A. The most feasibly detectable level utilizing the phase contrast microscope.

15 Q. Yes, we've gone through that, and I meant to stipulate 'based on the phase contrast microscope'.

A. Right.

Q. As we went through just before the break, that number could in theory be even lower based on what is detectable, were a lower level detectable?

A. It could well be.

20 Q. Let's talk about the benzene case for just a couple of minutes. Mr. Laskin gave me the opportunity to do so.

I take it, or I know this time, that NIOSH published a criteria document for benzene?

25 A. That is correct.

Q. That criteria document was published, I think, in 1976? It has published previous ones, but it published its last one in 1976, correct?

A. I believe that's correct.

30 Q. In that case, in that criteria document, it was modelled on basically the same kind of approach which our criteria document for asbestos is, namely, the criteria document





5 Q. (cont'd.) concluded that benzene was a carcinogen, in that case a leukemogen, and secondly that there was no level, no safe level in the sense that there was always additional risk at any level, and third, that exposures ought to go down to the lowest feasible level. Is that a fair statement?

A. It's a fair statement, to the best of my knowledge.

10 Q. That criteria document, therefore, recommended reducing the occupational level from ten parts per million to one part per million?

A. I believe that's true. I did not personally have an involvement in the development of that document.

15 Q. That case, as we all know, was litigated and eventually the Supreme Court overturned OSHA's attempt to reduce the standard from ten parts per million to one part per million, correct?

A. That's correct.

20 Q. You testified this morning about how that decision has affected the way NIOSH prepares criteria documents, and I take it that is because the court concluded that OSHA must demonstrate, in order to reduce that level from ten to one, that there is a significant risk, not just any risk, but a significant risk at ten, and that the use of quantitative risk assessments was an appropriate way of addressing that question.

A. That's my understanding.

25 Q. So that the three-pronged premises upon which the benzene criteria document was based were significantly altered by this Supreme Court decision, and that is what has caused you to change your practice from here on out in developing criteria documents?

30 A. I think it's fair to say that the benzene decision certainly had that impact.

Q. I guess it's fair to say also that were a new



Q. (cont'd.) criteria document developed today, that it would contain quantitative risk assessments, among other things, for asbestos?

5 A. That is correct.

This, by the way, does not...is not a criteria document. This is a committee report. But if we were developing a new criteria document, with a recommendation to a standard to OSHA, we would include a quantitative risk assessment in that recommendation.

10 MR. LASKIN: Could you identify that for the record?

MR. WARREN: That? Oh, I'm sorry. Tab eleven.

MR. WARREN: Q. It's probably good to point out that distinction that you have made so that we don't all misstate it.

15 Am I correct that the 1976 document is a criteria document, the 1980 document is essentially a committee report which carries forward the criteria document which previously was outstanding, or...

20 THE WITNESS: A. It carries forward the previous 1976 criteria document, with additional recommendations and some alteration in the medical surveillance and other activities. But it is not a criteria document in itself.

Q. But were we to have a criteria document for asbestos in the way with benzene, it would have a quantitative risk assessment?

25 A. That is correct.

Q. That kind of assessment would attempt to look at what degree of disease was produced at what level of exposure?

30 A. That is correct. I think there is one statement that I would make, and that is if we are making a criteria document with a recommended level for a particular





5 A. (cont'd.) substance such as asbestos, it would have a quantitative risk assessment. If we were putting a criteria document out that was dealing with just recommendations for a standard for control technology, work practices, etc., it would not necessarily have a quantitative risk assessment because you would not be recommending a level at which you would address risk.

10 Q. That's a good point to make right at this point.

Because you are not here to speak for the new director of NIOSH, one possibility is that we will have a new criteria document for asbestos, containing a quantitative risk assessment which might reach different conclusions.

That's a fair statement, isn't it?

15 A. I cannot predict what the new director will do. He might well do that.

20 Q. Another possibility, and I would like to explore this one in a little more detail, is there could be another criteria document, a new one, which wouldn't recommend a level at all, might not have a quantitative risk assessment, but which would address some of the things you were talking about this morning, that is, work practices and means of controlling exposure?

25 A. That could well be true. Again, emphasize there is nothing in the works in our Insitute, except for the mining criteria document, on asbestos at the present time, nor is there any intent, in my mind, to put out a new criteria document on asbestos...for the general industry.

Q. Right.

30 But it is true, is it not, that the criteria document which you just issued for asbestos in 1976, and the following one in 1980, made no attempt to address the significant risk question required to be addressed by the Supreme Court,



Q. (cont'd.) nor to prepare a quantitative risk assessment dealing with that issue?

5 A. The 1976 document certainly did not do that. There was a statement that was made in the 1979 committee report, if I can find it, page 30, section eight, just dealing with dose-response relationships. But in no way was that adequate for a quantitative risk assessment. But it did address the idea of a dose response, which we had not addressed in that much detail in previous publications.

10 Q. But no attempt was, no formal attempt such as you are talking about in the mining criteria document was made, nor was any attempt made to say whether or not the levels that you were talking about were significant in the sense that the benzene Supreme Court decision was?

15 A. If you relate it to the benzene Supreme Court decision, no.

20 Q. Now, let's talk about the option which you alluded to this morning and I just addressed a minute ago, and that is dealing with asbestos exposure in terms of not a permissible exposure level, but instead in terms of work practices or controls within the work place which weren't tied to any specific permissible exposure level. That is in keeping with the approach which you people are considering in general, I guess, you testified about this morning. Is that fair?

25 A. We are considering, in general, to make a much stronger emphasis in the area of control technology, and the areas of work practices and combinations of the two. I did not say...I don't believe I said, that we would completely go away from a TLV type of approach, particularly when we are dealing with asbestos, one substance. We have that ability to talk about the TLV, as compared to the general quagmire of chemicals that appear in the petrochemical industry where we  
30 may well not have that same option. So it will be handled on



A. (cont'd.) a basically one-by-one basis, that decision.

5 Q. Let me...you alluded to this morning the possibility of co-operative ventures with industry to attempt to ascertain controls or work practices which might be effective in eliminating unnecessary exposures. Did you intend that remark to apply to the asbestos industry as well as the other industries you have discussed?

10 A. Certainly. It has long been my opinion that co-operative programs between labour, industry and the government are the most effective way to approach public health. That standing over people with a large hammer and beating them on the head is not necessarily the best way to approach correcting a hazardous situation. That if you can bring all the parties  
15 involved into a co-operative discussion, I think that you will have much better progress in reaching the goals of public health than to simply come down with regulation after regulation after regulation.

20 Q. One of the questions which Miss Jolley brought up earlier this afternoon was the construction industry, and I think we both agree that the construction industry is presently covered by the two fiber standard in the United States?

A. Yes.

25 Q. Would your remarks about consideration of joint industry/government investigations, and so forth, of feasible work practices or controls apply to that phase of the construction industry as well?

A. It could well apply to that phase.

30 Q. In other words, an appropriate way of looking at the construction industry might be the development of a system of work practices which could be used to control exposures in the construction industry work place, so as not to require a permissible exposure limit?





5 A. I think that the industrial hygienists in both industry and government, when you are talking about one substance, would like to have some level to design their engineering controls and their work practices towards. I think that work practices alone, which you are just discussing, are not adequate. I think that you have to build into the whole system the engineering controls, and that the industry has the responsibility for providing those type of controls to go along with the work practices.

10 I interpreted what you just said to be putting the burden purely on work practices, and I would not agree with that.

15 Q. Let me ask the question...and I don't want to argue the issue ...if one is talking about the construction industry use of A/C pipe, asbestos cement pipe, where the exposure to that asbestos, if it occurs or where it occurs, is generally in the installation of the pipe or the cutting of the pipe, apart from work practices, what kinds of engineering controls have any application in any event?

20 A. Well, certainly, again, I will not attempt to be an expert, but certainly the employer can provide certain areas at the work site - portable enclosure systems to enclose the area when you are doing the sawing, certain vacuum systems to put onto the saws that pull as much of the dust away from the exposure zone of the worker as possible, and those are certainly things that are portable measures that can be attached to equipment.

25 It's the same as a sanding, a piece of sanding equipment where you have a portable vacuum cleaner attached to it. That is an engineering control.

30 Q. Maybe we are hung up on definitions then, because...are you aware that the Asbestos Information Association has submitted, over a year ago, to OSHA and to the construction industry advisory committee, a recommended alternative standard for application in construction industry work places which looks



Q. (cont'd.) at the alternative of work practices broadly defined to include equipment design changes, such as you are referring to?

5 A. I am aware of that.

Q. Is this the kind of co-operative industry proposals which you think are positive and in the spirit which you alluded to earlier?

10 A. I certainly think it is going in the right direction to talk about equipment changes, engineering controls. Many of our health problems have been eliminated purely by a simple equipment change, and outside the asbestos industry I think that the garbage industry, the refuse collectors - excess cardiovascular disease has been somewhat affected by just changing the exhaust system upwards instead of back towards the  
15 worker.

So I think that these are constructive and I would hope that more of these would be forthcoming from trade associations and industries and the labour movement.

20 Q. I guess you could summarize this line of discussion to say that this...without asking you to subscribe to the specific alternative recommendations which we have made, that's not my purpose.

The types of alternatives which we have been discussing are, in your judgement, one way in which NIOSH and then OSHA could go in regulating industry use of products...industry  
25 use of products such as asbestos-containing products?

A. I certainly think those are some of the ways. I would not say that that is the alternative way, or the ultimate way, but it's certainly an approach.

30 I think that..again, I must emphasize in the area of asbestos...if you do away completely with a level, those engineering controls may not be designed to be as effective as they should be, and I think that you have to weigh





5 A. (cont'd.) both of those areas a little bit together, because if you don't have some, and the industrial hygienists for industry are continually telling me this...that if they don't have...if they are dealing with one substance and they don't know how far down you should get it, it makes it very difficult for them to design those engineering controls.

10 So I still talk about our lowest feasible level when we are dealing with a carcinogen, in designing the controls to bring it down to that.

15 Q. First of all, we shouldn't get into the AI alternative proposal, because I don't want to leave the impression that it doesn't have a PEL contained within it...

A. I thought it did. That's why I made that point.

20 Q. Yes. Let's both of us not leave the record unclear on this issue.

25 When we talk about the way in which we are to regulate, and after the benzene decision and after the sort of endorsement of the quantitative risk assessment approach as a way of looking at this issue, I think you said that you supported that kind of approach? That you endorse that philosophy. Am I right?

A. Repeat that again, exactly.

30 Q. Maybe it's convoluted, the way I said it. I realize that and I apologize for that.

In response to a question from Mr. Laskin this morning, you alluded to the fact that in the wake of the benzene decision NIOSH had changed its way of doing criteria documents to include quantitative risk assessments, correct?

A. That's correct.

35 Q. And that's in order that NIOSH can attempt to comply with the benzene decision and help OSHA comply with the benzene decision?



A. That's correct.

Q. I think you said that you supported and favoured and felt that was a good development, a positive development in this area?

A. From my own personal point of view, I feel that putting quantitative risk assessment adds a dimension that we had not had in the past, and I feel that is a good step in the right direction.

That's my personal point of view and does not necessarily represent the opinion of the federal government of the United States.

Q. At least the old federal government, that's true.

Now, we talked a little bit about the Simpson Report this morning. I know you expressed some differences of view with the Simpson Report.

A. That's correct.

Q. One of the things which you mentioned was that you felt that the Simpson Report didn't pay sufficient attention to the IARC criteria document. Is that correct?

A. I don't think it was necessarily the IARC criteria document. If it came out that way, it was somewhat incorrect.

I feel the Simpson Report did not pay sufficient attention to the epidemiological evidence and weighing that evidence with the animal evidence. I think that the epidemiological evidence that the Simpson Report used included the same epidemiological evidence that we used.

However, I don't think they made the link with the animal experimental data, which I can give you, and I really didn't read anything, but I did prepare a little thing to read that I could give you, if necessary, about the animal evidence and how it links to the 'epi' evidence that led us to the



A. (cont'd.) conclusion that chrysotile should not be regulated more or less stringent than crocidolite or amosite or the other...

5 Q. That's what I'm getting to. The differences which you have with the Simpson Report, at least the ones you were discussing this morning, relate to the issue of how one regulates crocidolite, is that true?

A. How one regulates chrysotile.

10 Q. Or...well, I'm not sure that's not the other side of the same coin. In other words...

A. I'm not so unhappy with the Simpson Report on how they regulate crocidolite. I would like to see them bring the chrysotile into the same type of regulatory climate that crocidolite...

15 Q. But your point is the distinction between the two, you feel, is not...?

A. That's the major difference I have with the Simpson Report.

Q. Now, the Simpson Report does something that your criteria documents haven't done at all, isn't that correct?

20 A. It does a lot of things that we haven't done. I don't know what you are alluding to.

Q. Well, it does do a lot of things that criteria documents haven't done at all?

A. But our criteria documents have done a lot of things the Simpson Report hasn't done, and vice versa.

25 Q. That's...you could have one or the other, and I won't say which.

The Simpson Report, I believe, does do a quantitative risk assessment, which I think we have discussed previously here. Your report does not, does it?

30 A. Our report does not do one, that is correct. And the Simpson Report does do one with the data.





Q. The British anticipated the benzene decision and did a quantitative risk assessment which you people didn't do, right?

5 A. I don't know if the British anticipated the benzene decision.

Q. Well, I don't want to say they anticipated it, but...

MR. LASKIN: We can get you a special call over there.

10 MR. WARREN: Q. No, no. I just mean, the truth is that they did what you have not done, a quantitative risk assessment, right?

THE WITNESS: A. That is correct.

15 Q. Again, recognizing that you can't speak for the new director, and don't want to, I know, were you to do a quantitative risk assessment for asbestos, one can have no assurance that you wouldn't come out with respect to chrysotile exactly the same place as the British came out?

20 A. One cannot speculate that we would, but I think that we would take into consideration the animal studies, which the Supreme Court decision certainly left the door open to use animal studies in developing quantitative risk assessments. The Simpson Report did not really do that.

So I think that our differences would probably be evident in the same direction that our final results came out.

25 Q. Let me put it this way, I think we know what your personal views are. I think you have already stated what your personal views are, but I take it you are not suggesting that the scientists who prepared the Simpson Report and the quantitative risk assessment which underlays that report reached a conclusion which would be considered by all the scientific community to be unreasonable?

30 A. I'm not saying that at all. I'm simply saying



5 A. (cont'd.) that from my point of view, from our Institute's point of view, from our committee's point of view, the Simpson Report did not consider the animal data in developing the quantitative risk assessment.

10 Had we done a quantitative risk assessment like they had, we would have expanded it to include the animal data. The Supreme Court decision, it's my understanding, and you are far more experienced with that decision than I, does leave the doorway open to use animal data, and best available data, no matter whether it's epidemiological or animal data, to make a quantitative risk assessment.

We would weigh very heavily on the animal data.

15 Q. Let me ask you this. You know, we've had a number of witnesses testifying about this crocidolite issue and it's a tough issue, and I don't want to suggest that it's not a tough issue.

20 We've had some witnesses who say that where there is extensive epidemiological data, those data are almost by definition the best evidence, even if there is extensive animal data. You disagree with that, I take it?

25 A. I would say when there is extensive epidemiologic data with exposure measurements that are reliable attached to it, that that's very useful data to use and it's probably the most appropriate because we are dealing with the human animal as compared to the nonhuman animal, and of course I agree with your statement.

But I'm not saying that that is necessarily existent for human data in the asbestos industry.

30 Q. I think I understand that. I'm not sure. In other words, you are saying as an abstract proposition that if the human epidemiological data is ideal, then the animal data are irrelevant or at least of very distant secondary importance. But that may not be the case, in your judgement, for asbestos?





A. I do not think that is the case with asbestos.

Q. One of the things that has been discussed here several times today is the difference between, or the potential difference between, different industry segments. First of all between mining, and then downstream, industry. I take it you, from what you have said so far today, recognize that there may be some differences there?

A. Certainly.

Q. I take it the same applies among downstream industries? That is, that asbestos textiles may be different than asbestos cement pipe may be different than asbestos friction materials?

A. There would not be the same degree of difference there as between the general industry and the mining, but yes, there are some differences.

The way the product is contained in the pipe and the end use of that product probably presents a much less hazard than the way a textile product that contains asbestos presents a hazard.

Q. Dr. McDonald said something like this, in response to questions by me, he said that...putting aside textiles for a minutes...that if you look at the epidemiological studies for asbestos cement pipe and friction materials, they look pretty close to his own. But he felt that there might be differences in the textile situation. Would you subscribe to that?

A. Again, I missed a little bit. I didn't...say that again, please?

Q. It's too complicated a question all at once.

Let me make it a little bit less complicated. Dr. McDonald and I had a fairly long discussion about this, and Dr. McDonald said he felt that, if I can paraphrase him, and the record will show if I'm wrong, that there can be differences between mining, textiles, asbestos cement pipe, and so on and so forth?



A. I agree with that.

5 Q. You agree with that? I think he went further to say that when deciding about how to regulate...let me start off with...deciding how to regulate, he felt that one should attempt to look at the evidence which pertains to that industry segment. Do you agree with that?

A. In principle, yes.

10 Q. In other words, because we've had a long discussion about it today, for mining you think you ought to look at evidence on the risk in the mines and the mills?

15 A. I think you ought to look at that evidence, but I don't think that you can't supplement that evidence with other evidence from other particular uses. It would be like an ostrich putting their head in the sand not to look at the other health effects related to asbestos. But the area of difference between mining and general industry, I think you have to rely very heavily upon the difference in the fiber type, and is there an alteration to the fiber.

But the health effect, if you have the same type of fibers in the difference industries, should be the same.

20 Q. I thought we were working on the premise that they may be different?

A. I have said that. They may well be different. I don't have the data to back that up completely.

Q. I'm not sure really what you said.

A. Okay.

25 Q. What Dr. McDonald, I think, subscribed to pretty clearly...maybe even very clearly...is that when you are looking at mines, you ought to look at the mining studies; when you are looking at textiles, you ought to look at the textile studies, and they ought to be...if you have sufficient dose-response data, your basis for regulation. Do you agree with that?

30 A. I think, from an idealistic point of view, that



A. (cont'd.) what he is saying is somewhat correct, but let me qualify that.

5 If you show that the fibers in the mining situation are the same size, and have the same characteristics as the fibers in the general industry situation, you would really not be led to believe there would be a difference in the health effect in the mining as compared to the general industry.

10 I stated this morning that I thought there probably was a difference between those two fiber types, because of the milling of the fiber altering the fiber type. I am also saying that there are some other problems that, just looking at the mining studies, would tend to lead us to believe we are not completely convinced that the cohort was completely set up in the right way. There are other differences, but if the fibers are the same...and that's what you have to determine...if the  
15 fibers are the same, I don't see that you would expect to see a difference in the dose-response and effect of the disease outcome in either population.

Q. Your caveat is, if the fibers are the same?

A. And that's a very important caveat.

20 Q. I understand that's an important caveat.

But where there is, as you, I think, have stated, a strong suggestion that the fibers are different and indeed no proof that they are the same, would you then subscribe to Dr. McDonald's proposition, namely that you ought to look at the epidemiological evidence for the industry segment that you are talking about?

25 A. If the fibers are different. Is that what you are saying?

30 Q. No, I'm not saying...I'm saying...this is the world in which we don't all know the answers to all questions, and I'm saying this is the world where there is strong suggestion that there are differences, and certainly no evidence to prove that they are the same. In that situation, does one regulate





Q. (cont'd.) based on the epidemiological evidence which pertains to the industry segment in question?

5 A. I think that one regulates or makes recommendations, in our case, for regulation, based upon the total ballpark of information. But you certainly don't want to eliminate the other area, because it gets back down to the semantics of the whole argument that we are talking about - the difference in the fiber. But I wouldn't make a regulation and quote only those studies that were done in mining in a standard  
10 proposal that I would make. I would say that in the general industry we know that asbestos causes these type of problems, but we have evidence to believe that the fibers are different.

I think that that information all needs to be known.

15 Q. I'm not trying to hide the information, don't misunderstand my point. Let's assume that you put it all out on the table.

But ultimately, at the end of the day, people have to make decisions about where they are going to go, and I think that's what Dr. McDonald was referring to, not that we would,  
20 you know, erase the information and forget about it, but at the end of the day in trying to sift through all the information you have to look at what is key and what is secondary. In that situation, what one looks for are studies which have...which are good epidemiological studies with dose-response relationships established, and which pertain to the industry segment in question.  
25

Do you agree with that?

A. I don't necessarily agree that all the epidemiologic studies in the mining situation are adequate epidemiologic studies. I think they lack one, from not characterizing the fiber the way they should, and I still go back  
30 to that as being a key factor in making that decision.

Q. So you don't...you feel that Dr. McDonald's



Q. (cont'd.) study is inadequate then?

A. I think that Dr. McDonald's study of the chrysotile asbestos mining is inadequate to set a standard on, yes.

5 Q. Do you agree with Dr. McDonald's proposition that...again, I'm paraphrasing him and if I'm wrong, the record will show that I'm wrong...Dr. McDonald put a lot of emphasis on the need to attempt to characterize and quantify the best you can what the exposure was, and to attempt to establish a dose-response relationship. Do you agree with that?

10 A. I agree that that should be done.

Q. Do you think Dr. McDonald's study does that?

A. No.

15 Q. Do you think that..Dr. McDonald went over a number of studies that he felt did do that, and I take it...you have mentioned one today...that I think you think does that, and that would be Dr. Dement's study, right?

A. I think that his study of that particular plant does do a very good characterization of the type of...

20 Q. Are there any others?

A. I think we have much more information on the fiber size and diameter in most of the epidemiologic studies of the general textile industry as compared to the mining industry.

25 I think that the key question that we are bantering back and forth is that there is some question as to the difference in the fiber from the time it leaves the mine to the time it gets into general commerce. And I don't think that a lot of people who have made the studies did make those determinations and connected them with the epidemiologic studies.

30 Q. So I take it that leaves you very unimpressed with the epidemiology on asbestos, and the witnesses that we have had testifying here so far?

A. That I am unimpressed?

Q. Mmm-hmm.





A. I am not at all unimpressed. I would think that to explain the difference between mining and general industry that there is more information that needs to be collected.

5 Q. I wonder if...isn't that a statement that one can almost always make and scientists very frequently make just such a statement, namely that there is more information that we can learn about a subject?

A. Of course.

10 Q. We are beating a dead horse, I'm afraid.

Let me go to your gold mining study, but I wanted Dr. Uffen to be here when I covered one point. I think I'll...

DR. DUPRE: If you want that, would you mind if I took the ball for a moment to ask the following questions...

MR. WARREN: Sure, go right ahead.

15 DR. DUPRE: ...on the matter you raised, counsel?

Mr. Lemen, I have been following quite closely your point that you have made now, both to Mr. Laskin this morning and to Mr. Warren now, that in your opinion...and this is professional opinion, I take it...a deficiency in the Simpson Report, perhaps in Dr. McDonald's own approach, and some of his other colleagues in the field...a deficiency, in your professional opinion, is that all these committees or individuals have perhaps failed to weigh roughly equally or with due regard to their relative importance the animal studies and the epidemiological studies, is that correct?

25 THE WITNESS: That's a general feeling that I have, yes.

DR. DUPRE: Now, in coming to this conclusion or this feeling, I would imagine that you have thought through any of a number of the hypotheses that may or may not be lying around on the subject.

30 Could I ask if you have ever come across the following hypothesis, which is that especially if you want to



5 DR. DUPRE: (cont'd.) talk about asbestos type, crocidolite versus chrysotile, and so on, as I understand the hypothesis I'm going to put to you, it is to the following effect: It is that granted that the animal studies show similarly adverse effects whether it's chrysotile or crocidolite that has been injected, granted...those studies should be discounted when applied in the human realm, not because there is a difference between animals and humans, necessarily, at all, but because what you are looking at when you look at the human studies are effects from inhaling asbestos fibers in a working environment, and this hypothesis, as I understand it, would go on to say: a difference between crocidolite fibers and chrysotile fibers is that crocidolite fibers, for reasons that I don't recall, tend to settle...chrysotile fibers tend to settle more quickly, whereas crocidolite fibers float around in the air rather more and therefore would tend to be inhaled in proportionately greater quantities than would be the case for a similar number of chrysotile fibers.

Have you ever heard this hypothesis?

20 THE WITNESS: Taking...I think you made two points...one was that the animal studies could not necessarily be equated to the human studies because they were primarily injection studies. The studies that I refer to on chrysotile, while there were injections interpleurally, also were inhalation studies, and these were done by the Medical Research Council in Great Britain, which indicated that there was an excess of primary lung neoplasms in the animals that were exposed by inhalation. I refer to the Wagner studies, there were three of them...for which I give you a reference later, if you want... that chrysotile, in his conclusion, was as potent as crocidolite and other amphiboles in inducing mesotheliomas after interpleural injections, but also equally potent for inducing pulmonary neoplasms after inhalation exposures. And that was the conclusion



THE WITNESS: (cont'd.) of his finding.

So I contend that the animal studies are not all injection studies and would correct you on that point.

As to the second point, do the crocidolite fibers float around in the air more than the chrysotile fibers, I have heard of that, and we have found in our studies, at least the ones that I am aware of, that that has not necessarily been the case, but I must qualify that by saying it has been very difficult to find exposures where we have had just crocidolite as compared to chrysotile.

So that may be a misleading finding on our part, so I don't want to discount that theory, but again I think that the evidence that we have to day, through the inhalation studies, would be sufficient to at least draw that red flag as being a real problem.

DR. DUPRE: Thank you very much.

MR. LASKIN: I wonder...I don't mean to interrupt, Mr. Warren, but I wonder...

DR. DUPRE: Once any pitcher gives up the ball he has a terrible time getting it back.

MR. WARREN: That's right. It's a dangerous thing.

MR. LASKIN: I apologize.

But before I forget, in response to a question from Mr. Warren, you at one stage indicated you might refer to a document you had which tied together this link, I take it, between animal experiments and human...

THE WITNESS: What I can present to you, for the record, is a document that I wrote. I can also give you the second version of the document. There are two documents, one that I wrote and submitted to the Surgeon General of the United States, in response to an inquiry from Governor Babbit of Arizona, on chrysotile in his state, where a housing development had been built on a chrysotile deposit area, and the Surgeon General





THE WITNESS: (cont'd.) made some revision of that report and then sent a letter containing my summary to the Governor of Arizona, and I would be happy to give you both versions.

I think that the Surgeon General's version is a little bit more condensed from the version that I prepared to give to him, so the official version is the Surgeon General's version, the unofficial version is what I submitted, but I will be happy to make both available.

MR. LASKIN: That would be excellent.

THE WITNESS: I only have my version with me. I'll get the other and mail it to you.

MR. LASKIN: Can we give it a number as...

DR. DUPRE: May I advise you not to mail it to us? If you wish it to get here, maybe you can mail it to Mr. Warren's office and he can bring it up to us sometime.

MR. WARREN: Yes, I will be glad to.

MR. LASKIN: Will you permit me one further question?

MR. WARREN: Sure. I've lost my whole train anyway.

MR. LASKIN: Well, you reminded me of a question that I meant to ask this morning, which related to the Simpson Report and this whole discussion of fiber type.

As I understand it, the principal...and again, correct me if I'm wrong...or the report will correct me if I'm wrong...but the principal study that the Simpson Report looked at on the question of fiber type was the Enterline/Henderson study, because it was the one study that was able to look at, in one operation, the effects of crocidolite alone, the effects of chrysotile alone, the effects of amosite alone. Again, correct me if I'm wrong, as I understood it, one of the reasons...or in fact the main reason that the Simpson Report came to the conclusion of the recommendation it did was because there were differing risks shown in that one cohort study depending upon the different



MR. LASKIN: (cont'd.) fiber type exposures.

Have I misstated that?

THE WITNESS: That is true, to the best of my  
5 knowledge, in the Enterline/Henderson report. The one thing that  
I can't substantiate is that that was the only report they based  
it on. I would have to go back and refer to the study. It has  
been some months since I last read the Simpson Report.

MR. LASKIN: I guess my only question is, does  
10 NIOSH, or do you in your own professional judgement, have any  
view or comment on the reliability of that cohort study?

THE WITNESS: I think that it is one methodological  
approach. I don't think it's sufficient in its own light for  
the risk assessment that was needed.

I hope that's not too evasive an answer.

MR. LASKIN: Fair enough.

15 I'm sorry, Mr. Warren.

MR. WARREN: That's fine, that's fine.

MR. WARREN: Q. Let me see if I can sum up this  
area.

Is it fair to say that the underlying premise of  
20 the Supreme Court rejection of the benzene standard from OSHA,  
as recommended by NIOSH, was that we live in a society where  
there are risks which are acceptable, and risks which are  
unacceptable, and that the agency must do whatever possible in  
order to demonstrate at the outset that there is a significant  
risk presented at the present occupational exposure level, and  
25 that any reduction will constitute a significant reduction in  
that risk.

Is that a fair statement?

THE WITNESS: A. I think it's a fair statement  
to say the first part, that we live in a society that apparently  
30 accepts certain risks as being acceptable, other risks as being  
unacceptable.



THE WITNESS: (cont'd.) I would not go further than that with your statement, from an agency point of view and our point of view, or my own personal point of view. I am a paid  
5 and trained public health person, and I base mine on the public health risk associated, and I base that on the premise of the World Health Organization's definition of health, that it should not have any material impairment to any individual, no matter who they are. So I can't accept everything you said. I have to  
10 qualify it in saying that my recommendations as a public health official will be based upon what I think will protect the total population, no matter who they are or what their susceptibilities may be.

Q. In other words, is it fair to say then that you believe that an agency should be allowed to regulate or to  
15 reduce the level all the way down to zero?

A. I didn't say that.

Q. Well, I took that to be the premise, and the reason I said that was because you were saying that any additional impairment to any person, anywhere, constituted, in your  
20 judgement, a sufficient basis for taking action?

A. What I said was that as a public health agency charged with recommending public health policy or public  
25 health recommendations for standards, we would base it on the total health for the total population. I didn't say that a regulatory agency wasn't charged to take into consideration economic considerations, and I think the Supreme Court just made a decision on that, but to take into consideration other factors.

Q. Including the significance of the risk?

A. That is correct.

Q. That is the quantitative risk..

A. That's correct, and I don't deny that as  
30 being the role of a regulatory agency. I'm simply saying that's not our role.





Q. I take it that the quantitative risk assessments which you are now doing in connection with criteria documents are to assist OSHA in doing precisely that?

5 A. It will give OSHA and MSHA some basis on which to make their recommendations. They can look at the certain levels and say at this level we have this risk, and weigh in all of the factors that they, as a regulatory agency, have to weigh in.

10 Q. As we have discussed, and I don't want to belabour the point, but the Simpson Report did do a quantitative risk assessment, and I take it from the discussion we have had that the Simpson Report is different than your views on the subject because they rely on the human epidemiological evidence to make a distinction between the two fiber types, and then to do a quantitative risk assessment based on that evidence. Right?

15 A. I would say that I do not disagree completely with all the Simpson Report. I think there are very valid parts to the Simpson Report that are put together, and I think it's a well-written document. I disagree with the conclusions of that document separating different levels for different fiber types based upon the evidence that they presented, which I feel was inadequate.

20 Q. So you would argue they should have treated the two similarly?

A. The two?

25 Q. The two, chrysotile and crocidolite, let's say, or amosite as well, if you want to make it complete.

A. In my professional judgement, yes.

30 Q. Now, so a possibility is that treating the two similarly, one could conduct a quantitative risk assessment which would lead to the conclusion that a one fiber standard or a two fiber standard constitutes the level where risks are acceptable or risks are no longer going to be significant?



Q. (cont'd.) That's a possibility, right? If you do a quantitative risk assessment?

A. There is always that possibility.

Q. You people have yet to do one on asbestos?

A. That's correct.

Q. Okay. I actually was going to the gold mining study and I was waiting for you, because I want to clear up one subject that I'm not sure is absolutely clear.

We were talking about death certificates this morning, and we were talking about nosologists. Is it true that in conducting your epidemiological study, and indeed I guess you could go forward and say it's a standard practice in epidemiological studies that it is the nosologist that reads the death certificate?

A. In our studies, it's traditionally been in all of the studies that I've been involved in, the person that conducts the study. Obviously, I did not do a study without reading the certificates. The coding of the certificates, that decision is made by the nosologist. If I disagree with that coding, the nosologist's decision is the decision that I accept.

But that's not true with other studies.

Q. I understand. But in your judgement, the way in which epidemiological studies ought to be conducted is the nosologist is going to have the final judgement when reading the death certificates?

A. That's our opinion.

Q. Okay. Now, the data which the nosologist looks at is the death certificate and the death certificate alone, is that correct?

A. In our studies that's correct. We do not submit the pathology report or any other record to them.

Q. That, in your judgement, is the way it ought to be done? The nosologist ought to look at the death certificate, and the death certificate alone?



5 A. When you are making a comparison with another population, such as we did, that is true. I think the project officer or the epidemiologist has the responsibility to review pathology records, etc. and make those comments in the text of the article. But in no way should that alter the statistical difference between whatever comes up in the life table.

10 Q. Okay. So that in looking at the cohort population, the nosologist ought to look at the death certificate, the nosologist ought to make the decision interpreting that death certificate as to the cause of death, and that decision, in your judgement, ought to be the final word for purposes of comparison?

15 A. For purposes of comparison, but it does not say that you can't state in your text that the pathology report said something different. But for purposes of comparison you can't alter that. You have to have the nosologist make the final decision.

20 Q. The reason for that, as I understand it, is because the general population mortality figures are also based on a similar system where the nosologist reads death certificates, is that true?

A. That is true, but it may be more than one nosologist. The National Center for Health Statistics has a score of nosologists, compared to our small institute that has one.

25 Q. But, the point is, when doing a study, you want to have death certificates read by nosologists compared with death certificates read by nosologists, so that you are going to have comparability for purposes of comparison?

A. That is true.

30 Q. That's not to say that either series of data is correct in an absolute sense? That is, there may be misdiagnoses in both?





A. Certainly. But hopefully the degree of error in the misdiagnoses of both will be somewhat controlled by having nosologists make that decision.

5 Q. Now, in the text, I think, and this is why I just want to separate these two concepts out as best I can, not to make value judgements about any of them, you say that you see nothing wrong with, or it's appropriate for, or useful for the epidemiologist to consider all of the data which is available to him and to report in the text anything he knows about cause of death different than that which appears on the death certificate as read by the nosologist, correct?

10 A. That is correct, with ...and let me give you an example...if you are looking at a cohort of asbestos workers and you have some catastrophic accident occur, such as a bus accident in going up to the particular area, and you look at the pathology report and find that the cause of death is the automobile or the bus accident, but in reality seven of those persons had lung cancer, that is a significant finding to note in the text, but you can't use that...they would be coded out as having died in an accident, and that's how they would be compared with the other population.

15 But I think it's significant to note that that was a pre-existing condition.

20 Q. It's important to note, but you shouldn't use it for purposes of comparison because you can't do the same thing with your general population comparison data?

25 A. But at no time have I said we would use it for purposes of comparison.

30 Q. I'm not trying to, you know, throw any stones or anything like that. I'm just trying to clarify the concept. You wouldn't use it for purposes of comparison, you would note it so that the reader would understand that there was a bus accident and there were seven people killed and maybe if



5 Q. (cnt'd.) they would have died naturally, rather than in an accident, you would have had a higher number? Is that...but you would report that, but you wouldn't use it for comparison purposes, right?

A. That's correct.

Q. And the reason why you wouldn't is because you cannot do the same thing for the general population mortality data which you are using for comparison purposes?

10 A. That is correct.

Q. Now, the gold mining study that we were discussing this morning. I believe that's...

DR. UFFEN: Tab three.

MR. WARREN: Q. You, I think, told us that that study was quite controversial. Fair statement?

15 THE WITNESS: A. True.

Q. It is true, is it not, that Dr. McDonald looked at the same mine in the same...the same Homestead Mine in South Dakota, after your study and concluded that there was no excess incidence of respiratory malignancy and asbestosis?

20 A. That is true. Home State Mine, however, the cohorts differed in selection criteria.

Q. Cohorts overlapped though?

A. They did overlap. His was a larger cohort than ours.

25 Q. All right. Dr. McDonald's study is tab sixteen in his exhibit number, which is number...it's exhibit eighteen, I'm sorry. Exhibit eighteen.

I take it you have read Dr. McDonald's study?

A. Yes.

30 Q. Would it be fair to say that since Dr. McDonald's study was conducted subsequent to yours, that one of its purposes was to ascertain whether, with this larger cohort, he would find the same excesses which you had previously reported, you and



Q. (cont'd.) your colleagues?

A. That would be my presumption as to why he would do it.

5 MR. WARREN: I wonder...we probably don't have copies of it. I think it might be useful, though, to refer to page 276. But I'll bet nobody has it.

DR. UFFEN: McDonald?

MR. WARREN: McDonald.

DR. UFFEN: All upstairs.

10 MR. WARREN: This is the McDonald study entitled, Mortality after Long Exposure to Cumingtonite-Grunerite. It's in the American Review of Respiratory Disease, 1978.

MR. LASKIN: I think it's fifteen.

15 MR. WARREN: I thought I said fifteen, but maybe I said sixteen. This one says sixteen right on it, that's what confused me.

MR. LASKIN: Why don't I at least give it to the witness?

MR. WARREN: All right.

DR. DUPRE: We're at tab fifteen, the McDonald study.

20 MR. WARREN: Q. I wonder, Dr. Dement, (sic) whether you could turn to page 276.

Oh, excuse me. I called you Dr. Dement. The reason I did so was I was shuffling, thinking, I want to call you Dr. Lemen, and not...anyway.

25 THE WITNESS: A. He could probably give you much better answers about this study, so if you want to wait and talk to him about it, that's quite relevant.

Q. I wonder if you could take a quick look over that page.

A. Any particular part of the page?

30 Q. Well, would it be fair to say that the entire page, really, virtually anyway, is addressed to attempting to explore whether Dr. McDonald could have overlooked anything





Q. (cont'd.) which would make your observation correct, and simply overlooked in his data?

5 A. I think maybe the relevant paragraph to look at concerning Dr. McDonald's study is the top paragraph on the righthand side of the page where he talks about starting with:

"Thus men who survived twenty-one years in a mining company will not include those killed or disabled during the qualified period, or men who for physical or psychological reasons found the work unattractive.

10 On the other hand, occupational cancers, especially those associated with asbestos seldom kill within twenty-one years of first exposure. Thus, a cohort such as the one we studied should be at least as likely to demonstrate excess mortality due to malignant disease as the Gellman and Associates, which included a man with as little as five years employment.

15 Conclusions from the latter study are weakened by the author's observation that the odds ratio for deaths from respiratory malignancies was greater within the twenty years of first employment, five point four four, and then after at three point two".

20 Q. Let me stop you for a minute and ask you a couple of questions about that.

25 A. Okay. I was developing my argument, but I'll let you develop yours.

Q. I want to make sure that we understand Dr. McDonald's statements first.

30 Dr. McDonald, I think, is saying that because of the size of his cohort and also because he doesn't have people in that five to twenty-one year period, that he is more likely, if



Q. (cont'd.) anything, to uncover an excess than you are. That's the first proposition.

A. That's the proposition Dr. McDonald makes.

Q. And you disagree with that?

A. I disagree with it from the point of view that he had essentially looked at a survivor population. You had to live and work at least twenty-one years, or twenty years in the plant, in the mine, to even be included in the population. It's not taking into account latency considerations.

I think that in our consideration we were taking people that had the shorter exposure periods, and looking at those. I think that the survivor populations have been shown to be somewhat biased in their detection of disease.

Q. Wait a second here. I'm having trouble with this, because I thought it was a fairly common approach to attempt to consider in an epidemiological study those workers exposed only, in only X years, usually ten, fifteen, twenty years, after first exposure...twenty-five sometimes. True?

A. Exposed...you are talking about latency, I think.

Q. Yes.

A. You are confusing the two. This is not latency. This says they had to work at least twenty-one years. That's different. That's different than latency.

Q. Well, Dr. McDonald is saying that for that reason it is even more likely, he feels, that he would uncover something.

A. I disagree with that. They had to live at least twenty-one years. That's different than a latency of twenty-one years.

Q. Well, that's right. But it's also true that those people who had not...in many epidemiological studies...who died more than X years, twenty years, let's say, after first exposure, would be excluded in order to take a latency period into account?



A. Say that again? I just, for some reason, lost the last part of what you just said.

5 Q. Well, taking a latency period into account frequently results in withdrawing from consideration persons who die shortly after first exposure?

A. Taking latency into account frequently excludes...

Q. Right.

A. ...people that die shortly after first exposure?

Q. Right.

10 A. Certainly it controls for that.

Q. Right. Which is another way of saying what he is saying.

A. No.

15 Q. Let me ask it another way, because he supports his observations here by saying that a particularly difficult thing to understand about your study is that you have a higher relative risk for people exposed for less than twenty years, or twenty years after first employment, than you do for those exposed thereafter.

20 Do you see that as an anomaly, and as inconsistent with the kind of dose-response relationship that one expects?

Am I right about that?

A. Let's see...I'm trying...

Q. I'm talking about the last sentence of the paragraph which you read.

25 A. He is saying that they are weakened by the author's observation that the odds ratio for death from respiratory malignancies was greater within, prior to, the twenty years period of first employment than after the twenty year period.

30 I don't find that in the studies that we have done at our agency. There tends to be sometimes a peaking out and then a decreasing, and the longer you get away from the original exposure, the odds ratio doesn't necessarily get larger in those





5 A. (cont'd.) lighter periods. It tends to start going down, and in our assessment we have seen, you'll have a high odds ratio for asbestosis in the earlier years, the lung cancer will start peaking out say at fifteen years, and then the mesothelioma will start peaking out later, and the others will start dropping back. So I don't find that to be a disqualifying factor about that.

Q. We are not talking about...

10 A. I find it to be very surprising in that we have had such a high odds ratio prior to twenty years, that he must have missed something.

Q. Let me see if I understand this. While Dr. McDonald believes that ...

DR. MUSTARD: Can I interrupt for a moment?

MR. WARREN: Surely.

15 DR. MUSTARD: Just straighten me out. It's, you know, five-thirty and teatime in England, but on table two on 339 of tab three, if I read it correctly, I may have misunderstood what you said in your question, observed over expected...oh, I see what you are getting at. Yes.

20 Is there a big difference there? It's four to two point one four, and eleven to seven point five nine.

THE WITNESS: What Dr. McDonald's...

DR. MUSTARD: I am looking at tab three, the Gillam study that you are referring to, and...

THE WITNESS: Actually, I...

25 DR. MUSTARD: What you are saying is that there is a big difference between the people over twenty years of exposure, they show much less than the people over twenty?

THE WITNESS: Right.

DR. MUSTARD: Is one of those very big differences?

30 THE WITNESS: Well, Dr. McDonald thought they were significant enough.

Here's the numbers which he quotes, and I had to



THE WITNESS: (cont'd.) play them back into the Gillam table, so I can't tell you which table they refer to.

But McDonald says that those persons exposed... death from respiratory malignancy was greater within twenty years of first employment, per annum, five point four, than after it, three point two. Dr. McDonald's statement here is, that...

DR. MUSTARD: Can you give me those figures again?

THE WITNESS: Yes. It's five point four - that's the odds ratio for those people before twenty years, and three point two is the odds ratio for those after twenty years.

Now, I have not gone back to verify whether Dr. McDonald's numbers there are accurate.

DR. MUSTARD: That's for the respiratory system?

THE WITNESS: Respiratory malignancies.

DR. MUSTARD: Okay.

THE WITNESS: Not for asbestosis.

DR. MUSTARD: All malignancies?

THE WITNESS: Yes.

DR. MUSTARD: Okay.

THE WITNESS: Got it?

DR. MUSTARD: Yes, thanks.

MR. WARREN: Q. Let me see if I can summarize - you disagree with Dr. McDonald that the lower odds ratio after twenty years from first exposure weakens your study?

THE WITNESS: A. I disagree with that.

Q. Okay.

Did Dr. McDonald's contrary conclusions, from a larger cohort, contribute to the decision that your data ought to be reanalyzed by an outsider?

A. I can't remember if that decision was made prior to the publication of Dr. McDonald's study, or whether it was made after the study, but the...let's see...it was in 1978 that



5 A. (cont'd.) he published it, so it was apparently made prior to the publication of this study, but there were comments from Johns-Manville which I would have no objection to entering into the record, Johns-Manville's comments and our rebuttal to those comments about this particular study.

I don't know if Dr. Chase would have any problem with that, from Johns-Manville's point of view.

10 Q. The only thing is, we are not talking about Johns-Manville's comments on your study. We are talking about Dr. McDonald's study.

A. But I think Johns-Manville comments probably had more to do with the decision than Dr. McDonald's study, is the point that I am making.

15 Q. I see. You are saying that Johns-Mansville's criticisms of your study...

A. Johns-Manville's criticisms came much sooner after the study was published, and the McDonald criticism came, I think, as a result of industry asking him to reanalyze and look at that cohort.

20 So I don't think that McDonald's study was the main factor that caused our director to make a decision to go out and have another study done.

Q. You know, that's not what Dr. McDonald says. He doesn't say anything that he is doing this at the instance of industry.

25 Let me refer you to page 272. Are you with me?

A. Yes.

30 Q. He says in that first full paragraph, that he began working on this cohort and he didn't have support to carry through everything he wanted to do. Then you people reported your results in 1974, and then he says in the last sentence: "This indication of risk and the importance of the question prompted us to complete and analyze our





Q. (cont'd.) "initial survey with our own resources, without proceeding to the more extensive study originally planned."

5 A. I can only say that I think that when we started doing our study that the industry was as interested in getting a study done, that that is the time they approached Dr. McDonald. I cannot tell, what it says in writing is clearly the evidence at hand, I can only tell you my understanding of the chain of events that occurred.

10 Q. I'm not sure that I understand that answer.

Are you saying that you believe or disbelieve what Dr. McDonald says here? That it was with our own funds or our own...

15 A. Well, I can't say if it was his funds or not his funds. I am not here to debate that. I'm simply saying that I think that he initiated his study as a result of the fact that NIOSH was also doing a study in the same mine.

Q. I think he says that.

A. That's all I'm saying.

Q. I think he says that.

20 A. I don't think I said the company necessarily paid for it, but I think the company approached him to do the study.

25 Q. Okay. But I guess we can sum up by saying that Dr. McDonald did a subsequent study of the larger cohort which didn't find the excess incidences of respiratory problems which you found, and that he makes a good faith effort to reconcile your study and his own. Fair statement?

30 A. On his part, he makes a good faith effort to do that. We happen to disagree with his good faith effort, that there are certain problems with his study that invalidate it - that being it's a survivor population. I think I explained what I meant by survivor population.



A. (cont'd.) No matter how many numbers he puts, if he doesn't put the people that are really at risk, he can show anything you want with an epidemiologic study.

5 Q. And I don't want to continue to beat this poor dead horse, but...

DR. UFFEN: Fine.

MR. WARREN: I'm sorry.

MR. WARREN: Q. But, that means you disagree with his conclusion that his population is more likely to show an excess?

10 THE WITNESS: A. I stated that at the beginning, yes.

Q. But whenever you, you know, dangle on the end a qualifier, then I've got to bring forward a qualifier of...

A. All right. Now I'm making no qualification. My personal opinion, and the opinion of the other authors of our paper, indicates that we disagree with the results of Dr. McDonald's study.

15 Q. One final thing. A number of witnesses, and I don't think Dr. McDonald is alone on this...Dr. Weill, Dr. McDonald, I think Dr. Enterline too, testified that on the issue of gastrointestinal cancer that the evidence is in some disarray.

20 Some studies have found such an excess incidence, some studies have not.

Earlier today, I think I heard you state it as a pretty much unequivocal proposition that there is such an association between asbestos and gastrointestinal cancer.

25 Am I wrong?

A. You are not wrong in any of the statements. I do agree with you, that some studies show it, some studies don't show it. And in our weighing the evidence we feel that there is sufficient evidence to presume that gastrointestinal cancer is a problem among asbestos-exposed workers.

30 So what you said was correct, both parts.



A. (cont'd.) There are also studies that do not show that mesothelioma or lung cancer are associated with asbestos. That doesn't mean that they are not.

5 Q. Those other witnesses that I referred to, I think Weill, Enterline, McDonald, and maybe others, would put this issue in sort of a different category than lung cancer. I mean, maybe so, maybe not.

You disagree then, in conclusion?

10 A. No, I think the...don't get me wrong...I think the highest risk factors for asbestos workers deal - asbestosis, lung cancer, mesothelioma. I think there is a lesser degree of evidence for the gastrointestinal, but I think there is strong enough evidence to go ahead and make the presumption that it is a problem, but the degree of association is not nearly as strong  
15 for the gastrointestinal as it is for the other three.

MR. WARREN: I think that's it.

DR. DUPRE: Thank you, counsel.

Any further questions from parties?

Mr. Ublansky?

20 MR. UBLANSKY: Short ones. I don't wish to cut into your time.

CROSS-EXAMINATION BY MR. UBLANSKY

25 Q. Tab eight, I believe, the hearings before the subcommittee, Dr. Merchant makes some reference to obstructive airways disease. He makes a statement that there is often airways disease associated with the inhalation of asbestos.

I wonder if that area has been pursued any farther since that particular statement. Can we make any more definitive statements with regard to obstructive airways disease and asbestos?

30 DR. DUPRE: Excuse me, counsel. What page at tab eight?

MR. UBLANSKY: Sorry. That was page 75, tab eight.





THE WITNESS: Can you tell me exactly where Dr. Merchant makes that statement?

MR. UBLANSKY: About halfway. "There is an increasing body of evidence that there is often airways disease associated with inhalation of asbestos."

That's the statement that I'm referring to.

A. That's on page 75?

Q. Mmmm-hmm. Tab eight.

DR. DUPRE: It's the second time Dr. Merchant's name appears.

THE WITNESS: Right. I see.

What I read him saying is that there are airways diseases associated with inhalation of these mineral fibers as well.

For some reason I'm not finding where you are saying...

Q. The sentence begins, "Asbestos probably not..."

A. "Asbestosis probably not.."?

Q. "Asbestosis probably not...", sorry.

"There can be a considerable degree of impairment associated with the inhalation of asbestos, not only fibrosis it causes, but there is an increasing body of evidence that there is often airways disease associated with the inhalation of asbestos".

A. I thought you had indicated obstructive airways disease. I don't see that in here.

Q. Perhaps I'm reading...that's what I'm reading into what he is saying.... reading into that, he means obstructive airways disease.

A. I don't think that's what he is saying. I think he is talking about more restrictive airways disease.

Q. Well, that's my question. If you are saying.. perhaps I'm misreading it then.



5 A. There are increasing bodies of evidence, Dr. Merchant's group on respiratory disease is looking at that. I personally have had no involvement in those medical studies, but both the MRC, it's my understanding, and NIOSH, are looking into those areas.

Q. But there are no definitive conclusions?

10 A. I think there are very definitive conclusions that there are airways diseases associated with exposure to asbestos. That was one of the first things that brought it to our attention, and the whole asbestosis issue, if you look at the definition of that disease.

Q. I'm thinking more in terms of something like bronchitis.

15 A. That's a hard question and not being a physician, I somewhat want to disqualify myself. There is some controversy about what you classify as bronchitis, and what is not classified. I think that you see it very predominantly in the British literature as compared to the American literature.

Q. I see. Okay.

20 Perhaps of a more general nature, we've heard a number of times that NIOSH has made some hundred and seven, I think you said, recommendations, of which about a dozen have been acted on. Does that...are you comfortable with that situation as a representative of NIOSH?

A. That's a loaded question.

25 Q. What I'm getting at is, if we, in this country, were to look at the type of agency that you are currently employed by...I suppose what I'm really saying is, if you had it to do over again, if it was 1970 again, would you design your framework the same way?

30 A. I think that our Institute was designed under a regulation that said we would do that. We carried out our responsibilities under that law, to the best of our abilities, in



A. (cnt'd.) making those recommendations.

It's a frustrating experience to our scientists and people that made those recommendations not to see them promulgated into a standard, but there is also the realistic side of the legal issues and the legislative issues that go into developing standards, and I can see it from both points of view.

But I think that our agency should continue to make recommendations, and make those recommendations so that they are useful to the industry and to the labour movement, and to interested and concerned parties. Even if they are not promulgated into an actual law, they should be written to such an extent that they are a good public health document that can be used even though it doesn't have the effect of being in play as a regulation.

Q. Based on your experience, would you... again, as I say...if you had to redesign it, and I'm just asking for your opinion now...but if you had to redesign it, would you change the structure?

A. I'll speak personally. I'm not going to speak as an institute.

My personal approach is to look at the total industry and to look at what is the real situation the worker is exposed to. I would approach the criteria document program a little bit differently. I think that the NIOSH criteria documents in the past, many of the earlier ones did not have sufficient epidemiology, that we should have concentrated a little bit more in that area.

I have made changes in the criteria document program to look more at the epidemiology and connect the epidemiology with the toxicology.

I don't think that that has always been done. I think that was somewhat a way that I would have designed it differently than the way it was designed, but that is my...again,





A. (cont'd.) quote, personal opinion. It doesn't represent anything but my personal opinion.

5 MR. UBLANSKY: Thank you very much. Those are my questions.

DR. DUPRE: Dr. Uffen?

DR. UFFEN: Mr. Chairman, I've had a couple of good questions earlier, so I don't want to take up a lot of time. But there is an area here where I think it would be a shame if we didn't ask the benefit of the opinion of our visitor.

10 I'm going to tab seven, where you have the, I gather, somewhat difficult, and maybe even unhappy job, of trying to summarize a discussion that took place subsequent to a group of papers concerning talc.

15 I read the discussions and I was unable to learn from it if there was an association of lung disability of any kind, with talc. What was the outcome?

THE WITNESS: I can say that there are associations of lung disease with exposures to talc, and we are talking predominantly of talc that contains fibrous material.

20 I did not write these sections. These were taken verbatim by a court reporter.

DR. UFFEN: You just wrote the cover at the front, did you?

THE WITNESS: I just sat down and listened, and when they came...

25 DR. UFFEN: I think you had to keep order.

THE WITNESS: I had to keep order with it, but in no way should it be construed that I wrote the words that appear on these pages.

30 Dr. Langer was given a copy of his speech, and he made the corrections and submitted it back to me as editor of this book, and the same is true of Dr. Kotin.

I didn't make changes on these documents, other than some of the editorial areas where commas were placed, maybe correctly



THE WITNESS: (cont'd.) or incorrectly...I hope correctly.

5 But, no, these represent the feelings of the speakers, but to answer your question, yes, there are problems associated with fibrous talc.

DR. UFFEN: Is there any sort of one general document that we ought to be looking at to find out what the results were then, because I wasn't able to glean it from all this.

10 THE WITNESS: Well, you could go back to the individual papers that appeared at this session.

DR. UFFEN: You have to read them all?

THE WITNESS: You would have to read them all.

15 There was also a symposium that was held, I believe in 1974, that might include some information on that, but I think you have to go back to the original papers to really get that information.

The discussion was designed to discuss, as we are doing today, the results of the papers.

DR. DUPRE: Dr. Mustard?

20 DR. MUSTARD: Can I begin with a question out of curiosity? It's in tab two, and it's on page 26 and page 43, with reference to Hoffman, who in 1918 reported that it was the practice of American and Canadian insurance companies not to insure asbestos workers due to unhealthful conditions in that industry.

25 Do you know anything about that reference? It's factual nature? Whether it's a good, solid reference or whether it's just an opinion?

THE WITNESS: I can give you a copy of the reference. Whether it's...I don't know.

30 DR. MUSTARD: Have you ever checked into it in respect...that is, have you gone back into the history of the



DR. MUSTARD: (cont'd.) U.S. insurance companies in 19...in respect of that paper? Has anybody ever done that?

5 THE WITNESS: There is a very good review that Peters and Peters puts out that I think mentions the same type of practice that had occurred. This information that I report comes from having referenced that document that Hoffman wrote.

I can't really say much more, but I could reproduce for you that information.

10 MR. LASKIN: I believe before we...I think we should willingly accept the witness's kind offer, because that document is, as far as I'm aware, nonexistent in this country. At least it doesn't...

15 THE WITNESS: I hope I'm not making an ill promise, because sometimes I go back to our files and things are not there, but I think that I can produce it for you.

20 DR. MUSTARD: Okay. The second question is, tab eleven, page fifteen..fourteen, fifteen, sixteen, seventeen... I guess, your use of the animal experimentation, and it has been very clearly and correctly articulated, in my view, why animal experimentation can be useful.

25 One of the problems you have when you are dealing with animal experiments is that human beings do not like to think they are rodents, and there is a much higher level of acceptability if you do experiments in animals which are closer to man...some people use pigs in my field, but the better ones are subhuman primates.

Has there been any work with asbestos done with subhuman primates?

30 THE WITNESS: There has been some work, and NIOSH is doing some of that work.

DR. MUSTARD: Similar affects as with the...?

THE WITNESS: We are not looking so much at a carcinogenic effect as we are the fibrotic effect, and some





THE WITNESS: (cont'd.) of the inhalation problems associated with it, because of the lifespan of that primate as compared to the lifespan of a rodent.

5 DR. MUSTARD: I see.

The second question is, in view of this fiber-size, fiber-type question which we were debating from the standpoint of epidemiologists today, and I might comment as I have listened to these discussions...if I may editorialize briefly, Mr. Chairman...it seems to me that this generates good work for lawyers and epidemiologists. That's one of those very useful functions in society.

10 But, has anybody done any animal experiments in which they take the story of the chryostile fiber in the mine site and then a processing site, and then give it to the animals to see if there is any difference? Has that been rigorously done as an animal experiment?

15 THE WITNESS: Not to my knowledge. I would ask the rest of the people in the audience if they know of any. I don't.

20 DR. MUSTARD: Just as an idle comment, it seems to me that's a very easy experiment to be done. It is surprising it has not been done.

25 Thirdly, in the animal experiments has there been any documentation of the susceptibility of animals in the toxicology experiments...most of us are quite familiar with the fact that there is genetic variation of susceptibility...has that been documented in all the animal experiments. Has anybody attempted to find out if breeds of animals are resistant versus those that are susceptible?

30 THE WITNESS: I think that some of the work that Stanton has done has outlined some of that.

DR. MUSTARD: Is that published?

THE WITNESS: The Stanton articles are published.



5 DR. MUSTARD: My final question is, the other part of the story when you are dealing with a variety of tissues in the body, not all tissues respond in the same manner. Therefore, has anybody carefully looked at the differences in the response of pulmonary tissue versus the gastrointestinal tract...in the experiments that have been carried out?

THE WITNESS: We had spoken earlier about that, I think. Privately...

10 DR. MUSTARD: I'm talking about the animal experiments, specifically designing studies to look at the variation in response in different tissues.

THE WITNESS: I'm not aware of that.

15 DR. MUSTARD: I just take as my example, radiation is known to have...to affect certain target tissues more than others, and when you are doing epidemiological studies, if you don't have fine tuning, it becomes very messy.

20 THE WITNESS: I think that the closest we can say that anyone has come to that has been some of the results that were presented at the Cardiff Conference two years ago, on the in vitro studies. That has published now, and there is some different tissue sites that have been exposed to asbestos, and that's, to my knowledge, the only place that that occurs.

DR. MUSTARD: That's in the Cardiff Conference?

25 THE WITNESS: There is a Cardiff Conference on the in vitro effects of mineral fibers, and there are some papers in that conference, I believe, that address that.

I can't tell you which ones without going to the reference.

MR. WARREN: I think, to add something, I think those papers are...I think papers of that nature are referenced in the Simpson Report as well.

30 THE WITNESS: I think the conference probably.

Most of the work in the in vitro effects, by the way, has been done with the MRC, and to a certain extent



THE WITNESS: (cont'd.) Ron Heart, who used to be at the University of Ohio in Columbus, but there has been very little and it's a very emerging field, and I just got an announcement that they are having the second international conference this coming year on the in vitro effects.

So I think that it's addressing what you are talking about.

DR. MUSTARD: My third question probably can't be answered because in a sense the previous question is related to it.

One of the other things which..again it's a note... do you know if there is any information on the question of fiber type and gastrointestinal tract cancer? I'm trying to get into the differentiation of response of tissues and transport.

Has there been any work looking at whether the differences in epidemiological studies could be related to (a) the type of fiber both in terms of basic mineral characteristics and fiber size?

THE WITNESS: In animals?

DR. MUSTARD: No, in humans.

THE WITNESS: In humans?

DR. MUSTARD: Are there any epidemiological studies in which you find a high incidence of GI cancer versus those in which you do not, and can you track into that study that there is some relationship to the kind of asbestos fiber both in terms of the kind of asbestos or fiber size?

THE WITNESS: Most of the studies that have dealt with that have shown excesses in gastrointestinal cancer tended to be mixed exposure, mixed-fiber exposures.

DR. MUSTARD: But has it tended to be in the textile industry more than in the other industries? Do you know...

THE WITNESS: That's a hard question to answer, too.





THE WITNESS: (cont'd.) I don't know that I can give you an answer right now. I would have to go back and look at the literature to make sure.

5 DR. MUSTARD: But NIOSH hasn't actually done that now?

THE WITNESS: No, we have not.

DR. MUSTARD: My next one is to turn to tab six on table seven. It's the mortality patterns among asbestos workers, and it's table seven. It's tab six, and it's the one  
10 by Robinson, Lemen and Wagoner.

THE WITNESS: Right.

DR. MUSTARD: And it's the mesothelioma table. The thing I want to get at there is that you have seventeen cases of mesothelioma...at page 139...and it says, "Number  
15 of years of employment".

Am I to believe that it's number of years of employment with exposure to asbestos? Is that what that means?

THE WITNESS: That's correct.

DR. MUSTARD: So you have three cases of mesothelioma with less than ten years exposure to asbestos.  
20 Is that the right conclusion to draw from that table?

THE WITNESS: That's correct.

MR. LASKIN: Four.

DR. MUSTARD: Are there four? Oh, yes. I put a circle around...thank you very much, counsel.

25 Okay, so that you have four with less than ten years exposure?

THE WITNESS: That's correct.

DR. MUSTARD: No history of earlier asbestos exposure among those workers?

THE WITNESS: Not to our knowledge from the records  
30 available to us.

DR. MUSTARD: Okay. My next one is to go to



DR. MUSTARD: (cont'd.) tab three, page 339, which is the one I think you were discussing earlier, and I just want to ask you a question about that.

5 Is one of the things...when you are doing statistical...or you are doing comparisons in terms of years of exposure and you have small numbers, then you run into the problems of the statistician, that there is safety in numbers and there is uncertainty in small numbers, and if you look at some of those comparisons that are present here...for example, 10 you take the malignant neoplasms in the respiratory system where you have three observed versus zero point five six expected, and seven observed versus two point one eight expected, has anybody ever done any comparison to find whether those differences from those two years really are significantly 15 different from each other? Whether that kind of ratio could have just occurred by chance? Have you ever analyzed the data that way?

In other words, are we making a mountain out of a molehill? Do you see what I'm getting at?

20 In other words, you've got a series of observations for the people under twenty years exposures, and a series for the people over, but the number of observations are actually quite small. The ratios that you get may look kind of nice, but statistically the probability of getting that just out of chance may be quite high, therefore it may not really be a 25 significant difference in ratios.

Has anybody ever analyzed the data that way?

THE WITNESS: I think that the type of analysis...

DR. MUSTARD: You may be perhaps on the wrong side of the coin to bring this up...

30 MR. WARREN: I think we need Dr. McDonald.



MR. WARREN: I would have honestly assumed that he had done that in reporting it. But I don't know the answer.

5 THE WITNESS: I don't know the answer as far as Dr. McDonald is concerned, but we take that into account in the type of analysis that we do.

DR. MUSTARD: But the statistical analysis is not to compare the under twenty versus the over twenty?

10 THE WITNESS: Yes, I know that. No.

DR. MUSTARD: You see, the thing I'm trying to get at...

THE WITNESS: I see what you are getting at.

DR. MUSTARD: ...is whether there is a difference there, statistically.

15 MR. WARREN: Let me say that in my question on this issue I presumed, without it saying expressly, that Dr. McDonald did that because it was my assumption he wouldn't make the point unless he had done that kind of analysis which occurred to me as well, but it seemed like it was sort of an obvious thing he would have done. But I'm not sure he did it. I just presumed so, since he made the point.

20 DR. MUSTARD: Then I guess if you have a certain amount of anxiety...

25 DR. UFFEN: You can get any results with an observation of three. If you plotted three points on a graph, you can draw any shape curve you wish.

DR. MUSTARD: I guess that concludes it. Thank you very much for bringing up those animals.

THE WITNESS: You are welcome.

DR. DUPRE: Mr. Laskin, any questions?

MR. LASKIN: No, Mr. Chairman.

30 DR. DUPRE: Mr. Lemen, you've had a long day, but





- 164 -

DR. DUPRE: (cont'd.) you've been most generous with your time, and most instructive.

I thank you very much indeed, sir.

THE WITNESS: You are welcome.

DR. DUPRE: We now rise until ten a.m. tomorrow morning, is that correct, counsel?

MR. LASKIN: That's correct, Mr. Chairman.

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THE INQUIRY ADJOURNED

THE FOREGOING WAS PREPARED FROM  
THE TAPED RECORDINGS OF THE  
INQUIRY PROCEEDINGS

Edwina Macht  
EDWINA MACHT







